Initial REMS Approval: 10/2010
Most Recent Modification: 7/2016

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

The iPLEDGE Program

Single Shared System for Isotretinoin

Reference ID: 3956479

1. GOALS

The goals of the isotretinoin risk evaluation and mitigation strategy are:

1. To prevent fetal exposure to isotretinoin
2. To inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions

2. REMS ELEMENTS

2.1. Medication Guide

A Medication Guide for isotretinoin is dispensed with each prescription for isotretinoin in accordance with 21 CFR 208.24, as described below.

A Medication Guide is enclosed with each blister package of isotretinoin to ensure that the Medication Guide is given to each patient with each prescription.

The currently approved isotretinoin Medication Guide is part of this REMS.

2.2. Elements to Assure Safe Use

2.2.1. Healthcare providers who prescribe isotretinoin are specially certified in the iPLEDGE Program.

a. Isotretinoin sponsors will ensure that healthcare providers who prescribe isotretinoin are specially certified in the iPLEDGE Program. To become certified, each prescriber must activate registration, by completing the Prescriber Enrollment Form, via the iPLEDGE Program website or the automated phone system. The registration and activation requires each prescriber to agree to do the following:

   i. Register each patient in the iPLEDGE Program via the iPLEDGE Program website or automated phone system.
   ii. Understands the risks of fetal exposure to isotretinoin and the risk factors for unplanned pregnancy.
   iii. Correctly identify and document patients as females of reproductive potential, females of non-reproductive potential, or males.
   iv. Provide contraception counseling to females of reproductive potential prior to and during isotretinoin treatment, or refer females of reproductive potential to an expert for such counseling.

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v. Provide scheduled pregnancy testing for females of reproductive potential and then verify and document the negative pregnancy test result prior to writing each prescription.

vi. Document the two chosen forms of contraception for each female of reproductive potential prior to writing each prescription.

vii. Prescribe no more than a 30-day supply of isotretinoin with no refills.

viii. Report any pregnancies in patients prescribed isotretinoin to the iPLEDGE Program.

b. Isotretinoin sponsors will ensure the iPLEDGE Program documents that certified prescribers/designees have performed the following responsibilities prior to initiating isotretinoin treatment and monthly prior to providing each prescription:

i. Counseled the patient about isotretinoin risks.

ii. Determined the reproductive status of all female patients prior to initiating treatment, and determined whether the reproductive status of female patients has changed.

iii. For patients who are females of reproductive potential, provide evidence or other documentation that prescribers/designees have:

a. Obtained a negative CLIA-certified pregnancy test result.

b. Determined that each female of reproductive potential has appropriate contraception and has been re-counseled about the importance of complying with contraceptive methods.

c. Isotretinoin sponsors will:

i. Maintain a validated and secure database of all iPLEDGE Program registered and activated prescribers, designees, and delegates.

ii. Monitor to ensure that only iPLEDGE Program certified prescribers are prescribing isotretinoin.

iii. Monitor to ensure that iPLEDGE Program certified prescribers correctly identify patients who are females of reproductive potential. A female of reproductive potential is defined as a nonmenopausal female who has not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure. This definition includes a young woman who has not yet started menstruating.

iv. Monitor certified prescriber compliance with the iPLEDGE Program. Certified prescriber compliance with the iPLEDGE Program includes categorizing female patient risk (females of reproductive potential vs. females of non-reproductive potential), providing counseling as required, documenting contraception forms as required, and providing pregnancy testing for all females of reproductive potential treated with isotretinoin.

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v. Institute appropriate corrective action according to the Non-Compliance Action Policy if the prescriber is found to be non-compliant with the iPLEDGE Program.

d. The following materials are part of the REMS and are appended:

i. *The Guide to Best Practices For the iPLEDGE Program*

ii. *Prescriber Contraception Counseling Guide*

iii. DVDs for prescriber use in patient counseling: *Be Prepared, Be Protected* and *Be Aware: The Risk of Pregnancy While on Isotretinoin.*

iv. Recognizing Psychiatric Disorders In Adolescents And Young Adults

v. Request for Exemption for Patients with Serious Medical Reasons

vi. Office Staff Designee Registration/Activation Form

vii. Instructions for Managing Office Staff Designees

viii. Prescriber Enrollment Form

2.2.2. Isotretinoin will only be dispensed by pharmacies that are specially certified in the iPLEDGE Program.

a. Isotretinoin sponsors will ensure isotretinoin is only dispensed by pharmacies that are certified. To become certified, the pharmacy must become registered and activated in the iPLEDGE Program. To become registered and activated, each pharmacy must identify a "responsible site pharmacist" who completes the Pharmacy Enrollment Form and agrees to do the following before dispensing an isotretinoin prescription:

i. Affirm that all pharmacists will comply with all iPLEDGE Program requirements**:**

1. Know the risk and severity of fetal injury/birth defects caused by isotretinoin.
2. Dispense only FDA-approved isotretinoin products and obtain isotretinoin only from the iPLEDGE Program registered wholesalers.
3. Do not sell, borrow, loan, or otherwise transfer isotretinoin in any manner to or from another pharmacy.
4. Dispense only to qualified patients determined via authorization from the iPLEDGE Program web- or voice-based system for every isotretinoin prescription.
5. Document the Risk Management Authorization (RMA) number on each prescription.
6. Dispense no more than a 30-day supply (no refills).

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7. Dispense the isotretinoin Medication Guide with each prescription.
8. Dispense prior to the "do not dispense to a patient after" date provided by the iPLEDGE Program.
9. Return to the manufacturer (or delegate) any unused product if registration is revoked or if the pharmacy chooses to not reactivate.

ii. Re-activate pharmacy iPLEDGE Program registration annually.

b. The following materials are part of the REMS and are appended:

i. Pharmacist Guide for the iPLEDGE Program

ii. Pharmacy Enrollment Form

2.2.3. Isotretinoin sponsors will ensure that isotretinoin will only be dispensed to patients enrolled in the iPLEDGE Program with evidence or other documentation of safe-use conditions.

a. Isotretinoin sponsors will ensure that all patients treated with isotretinoin are enrolled in the iPLEDGE Program by a registered prescriber, before isotretinoin is dispensed to them. To become enrolled, each patient or guardian must sign the appropriate Patient Information/Informed Consent form acknowledging that:

i. He or she understands the potential fetal harm with female patient exposure to isotretinoin.

ii. Enrollment in the iPLEDGE Program is required.

iii. Isotretinoin must not be shared with anyone, even someone with similar symptoms.

iv. He or she cannot donate blood while on isotretinoin and for 1 month after treatment has ended.

v. He or she must obtain the prescription within specified time frames.

b. Isotretinoin sponsors must ensure that isotretinoin is dispensed to females of reproductive potential only if there is evidence or other documentation that they meet the following safe-use conditions:

i. Are not pregnant or breastfeeding.

ii. Comply with the required pregnancy testing as ordered by the certified prescriber before receiving each isotretinoin prescription follows:

1. Two urine or serum pregnancy tests before receiving the initial isotretinoin prescription. The screening test and confirmation test must be at least 19 days apart. For patients with regular menstrual

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cycles, the confirmation test should be done during the first 5 days of the menstrual period immediately preceding treatment. For patients with amenorrhea, irregular cycles, or using contraceptive methods that precludes withdrawal bleeding, the confirmation test must be immediately preceding treatment and at least 19 days after the screening test.

2. Monthly pregnancy testing done prior to receiving authorization to receive each isotretinoin prescription.

iii. Unless continuously abstinent, comply with the iPLEDGE Program requirement to use 2 forms of contraception 1 month before, during, and for 1 month after discontinuing isotretinoin treatment.

iv. Access the iPLEDGE Program system before receiving each isotretinoin prescription and 1 month after isotretinoin treatment concludes to answer questions about the program requirements and to enter 2 chosen forms of contraception.

v. Be informed of the purpose and importance of providing information about her pregnancy, should she become pregnant while taking, or within 1 month of the last dose of isotretinoin.

vi. Be informed of the need to immediately stop isotretinoin treatment if she engages in unprotected heterosexual intercourse.

c. Isotretinoin sponsors will ensure that there is evidence or other documentation that all iPLEDGE Program safe use requirements have been met for each female of reproductive potential prior to receiving isotretinoin each month:

i. The patient is registered in the iPLEDGE Program and had required pregnancy test(s).

ii. The patient entered their two chosen forms of birth control into the iPLEDGE Program.

iii. The patient answered the required questions about the iPLEDGE Program and pregnancy prevention.

iv. The prescriber entered into the iPLEDGE Program the two chosen forms of contraception after re-counseling.

v. The patient has a negative pregnancy test result entered into the iPLEDGE Program by the prescriber or designee.

d. The following materials are part of the REMS and are appended:

i. Guide to Isotretinoin for Female Patients Who Can Get Pregnant

ii. Guide to Isotretinoin for Male Patients and Female Patients who Cannot Get Pregnant

iii. The iPLEDGE Program Patient Introductory Brochure

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iv. Isotretinoin Educational Kit for Males and Females of Non-Reproductive Potential

v. Isotretinoin Educational Kit for Females of Reproductive Potential

vi. Patient Information/Informed Consent for all patients

vii. Patient Information/Informed Consent for Females of Reproductive Potential

viii. Patient Monthly Comprehension Questions

2.2.4 Isotretinoin sponsors will maintain a centralized pregnancy registry for the iPLEDGE Program enrolled female patients who become pregnant and consent to participate in a root cause analysis.

The primary objectives of the iPLEDGE Program Pregnancy Registry are to:

a. Determine isotretinoin exposure status for each reported pregnancy.
b. Document the outcome of each isotretinoin exposed pregnancy.
c. Determine, document, and analyze causes contributing to fetal exposure (root cause analysis).

2.3. Implementation System

The implementation system will include the following:

a. Isotretinoin sponsors will maintain a secure web- and voice-based interface for all certified entities as described in Sections 2.2.2 and 2.2.3. This includes a system and process to monitor pregnancy testing results, and to link monthly prescription authorization (risk management authorization) to collection of the following data:

    i. Patient age, gender, and risk category

    ii. Required counseling

    iii. Prescription data (RMA numbers, dates prescription filled, quantities dispensed)

    iv. For female patients of reproductive potential:

        a. Baseline and monthly pregnancy tests, including 30 day post-therapy test (dates and results)

        b. Chosen methods of contraception

        c. Answers to monthly comprehension questions

    v. For females who become pregnant:

        a. Maternal and fetal outcome

        b. Information from the prescriber about circumstances contributing to the fetal exposure

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b. Isotretinoin sponsors will monitor wholesaler distribution data to ensure that only registered entities distribute isotretinoin. Wholesalers who distribute isotretinoin must be registered with the iPLEDGE Program prior to distributing isotretinoin and must re-register annually thereafter. Wholesalers must register with the iPLEDGE Program by signing and returning the iPLEDGE Program wholesaler agreement. By signing the agreement, wholesalers affirm that they will comply with all of the following iPLEDGE Program requirements:

   i. Distribute only FDA-approved isotretinoin product

   ii. Only ship isotretinoin to: 1) wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer; and 2) pharmacies licensed in the US and registered and activated in the iPLEDGE Program.

   iii. Notify the isotretinoin manufacturer (or delegate) of any unregistered and/or non-activated pharmacy or unregistered wholesaler that attempts to order isotretinoin.

   iv. Return to the manufacturer (or delegate) any undistributed product if registration is revoked by the manufacturer or if the wholesaler chooses to not re-register annually.

c. Isotretinoin sponsors will maintain a secure database of all certified pharmacies to ensure compliance with the following:

   i. Obtain isotretinoin only from registered wholesalers.

   ii. Dispense isotretinoin to patients only after receiving iPLEDGE Program authorization each month for each prescription.

   iii. Fill isotretinoin within the allowed timeframes only.

d. Isotretinoin sponsors shall develop and implement a single Non-Compliance Action Policy for handling noncompliant stakeholders.

e. Isotretinoin sponsors will monitor registered wholesaler and certified pharmacy compliance, address deviations, and institute appropriate corrective actions according to the Non-Compliance Action Policy if the wholesaler/pharmacy is found to be non-compliant with the iPLEDGE Program.

f. Isotretinoin sponsors will monitor the internet to ensure isotretinoin is not prescribed, dispensed, or otherwise obtained through the internet or any other means outside of the iPLEDGE Program.

g. Based on monitoring and evaluation of the REMS elements to assure safe use, isotretinoin sponsors will take reasonable steps to work to improve implementation of these elements, as applicable.

h. Isotretinoin sponsors will maintain a call center to support prescribers, patients and pharmacies in interfacing with the iPLEDGE Program.

i. The following materials are part of the REMS and are appended:

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i. iPLEDGE Program wholesaler agreement

ii. Wholesaler to wholesaler shipment request form

2.4. Timetable for Submission of Assessments (Applicable only to drugs with an approved new drug application (NDA))

The iPLEDGE Program assessments will be submitted to FDA on May 1, 2011 and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each annual submission will conclude no earlier than 60 days before the submission date for that assessment. The iPLEDGE Program assessment will be submitted so that it is received by FDA on or before the due date.

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The iPLEDGE Program

Prescriber Isotretinoin Educational Kit

The tools prescribers need to help prepare patients, plan treatments, and prevent pregnancies during the course of isotretinoin therapy

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

CONTENTS

- Guide To Best Practices For the iPLEDGE Program
- Prescriber Contraception Counseling Guide
- Recognizing Psychiatric Disorders In Adolescents And Young Adults
- Educational Video
- Prescriber Flowchart

iPLEDGE™

Committed to Pregnancy Prevention

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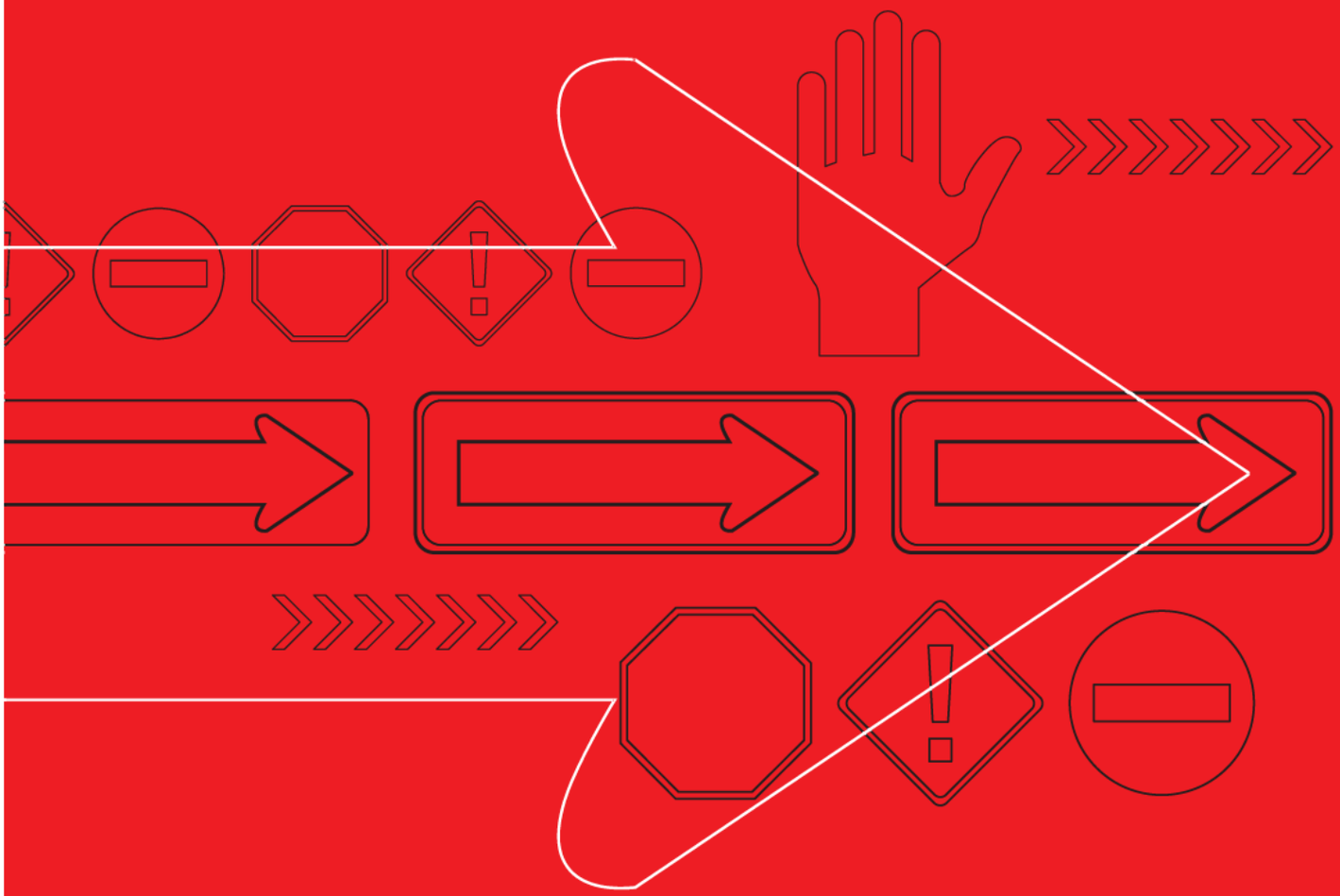
The Guide To Best Practices For the iPLEDGE Program



The primary resource for prescribing isotretinoin to ensure patients do not become pregnant during the course of therapy

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Most Recent Modification: July 2016

The iPLEDGE Program

The Guide To Best Practices For the iPLEDGE Program

The resource to help the prescriber prepare, plan treatments, and prevent pregnancies during the course of isotretinoin therapy

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

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Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. In addition, for female patients of reproductive potential, isotretinoin is indicated only for those female patients who are not pregnant (see boxed CONTRAINDICATIONS AND WARNINGS and PRECAUTIONS sections).

Important Facts About Isotretinoin

- Isotretinoin is highly teratogenic.
- Treatment with isotretinoin during pregnancy is contraindicated. Female patients should not be pregnant or become pregnant while on isotretinoin therapy and for 1 month thereafter.
- Fetal exposure to isotretinoin may result in life-threatening congenital abnormalities.

The Guide To Best Practices For the iPLEDGE Program

This guide has been developed to assist you in fulfilling the requirements for isotretinoin pregnancy prevention risk management. Please refer to the CONTRAINDICATIONS AND WARNINGS and the PRECAUTIONS sections of the isotretinoin Package Insert.

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see **PRECAUTIONS**).

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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ABOUT ISOTRETINOIN

Isotretinoin is used to treat severe recalcitrant nodular acne. Isotretinoin belongs to a class of drugs known as retinoids, commonly understood to include all natural and synthetic analogues of vitamin A. Therapy with isotretinoin should not be undertaken before conventional treatment has been tried first, including the use of systemic antibiotic therapy, and the patient has been fully counseled about the warnings and precautions in the isotretinoin package insert.

Isotretinoin is teratogenic and must not be used by pregnant women. Women should not become pregnant while taking isotretinoin or for 1 month after therapy is discontinued. A patient who becomes pregnant during treatment should stop taking isotretinoin and immediately contact her prescriber.

Isotretinoin use is associated with other potentially serious adverse events as well as more frequent, but less serious side effects. More frequent, less serious side effects include cheilitis, dry skin, skin fragility, pruritus, epistaxis, dry nose and dry mouth, and conjunctivitis.

Serious Adverse Event Warnings include psychiatric disorders* (depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors). Prescribers should read the brochure *Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of Isotretinoin therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary.

Other Serious Adverse Event Warnings include; pseudotumor cerebri; pancreatitis; hyperlipidemia; hearing impairment*; hepatotoxicity; inflammatory bowel disease; skeletal changes† (bone mineral density changes, hyperostosis, premature epiphyseal closure); and visual impairment (corneal opacities, decreased night vision).

Patients should be reminded to read the Medication Guide, distributed by the pharmacist at the time the isotretinoin is dispensed.

Pregnancy After Isotretinoin Therapy

The terminal elimination half-life of isotretinoin varies but is generally within 10 to 20 hours. The elimination half-life of one of the isotretinoin metabolites, 4-oxoisotretinoin, is approximately 25 hours. Since plasma elimination is host dependent, prescribers should warn patients not to become pregnant for 1 month post-treatment. Women who become pregnant during this month should be counseled as to the outcome data. In 1989, Dai et al reported the results of an epidemiologic study of pregnancies that occurred in women who conceived after discontinuing isotretinoin.[1] They studied women from 5 days to more than 60 days between the last dose of isotretinoin and conception. The incidence of birth defects in former isotretinoin patients was not significantly different from the rate in the general population.

* No mechanism of action has been established for these events.

† The use of isotretinoin in patients ages 12 to 17 should be given careful consideration especially when a known metabolic or structural bone disease exists.

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Isotretinoin is found in the semen of male patients taking isotretinoin, but the amount delivered to a female partner would be about 1 million times lower than an oral dose of 40 mg. While the no-effect limit for isotretinoin-induced embryopathy is unknown, 20 years of post-marketing reports include 4 with isolated defects compatible with features of retinoid-exposed fetuses; however, 2 of these reports were incomplete, and 2 had other possible explanations for the defects observed.

Birth Defects

There is an extremely high risk that a deformed infant will result if pregnancy occurs while female patients are taking isotretinoin in any amount even for short periods of time. Potentially, any fetus exposed during pregnancy can be affected. Not every fetus exposed to isotretinoin has resulted in a deformed child. However, there are no accurate means of determining which fetus has been affected and which fetus has not been affected.

When isotretinoin is taken during pregnancy, it has been associated with fetal malformations, and there is an increased risk for spontaneous abortions and premature birth. **The following human fetal abnormalities have been documented.**

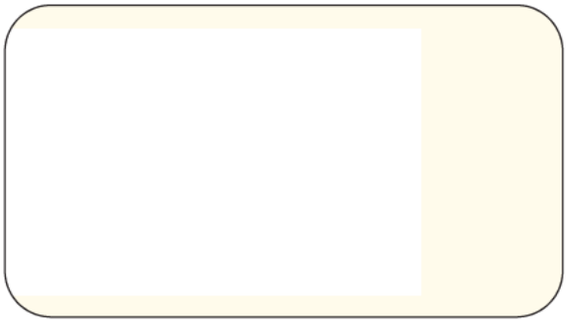
External abnormalities

Skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate.

Internal abnormalities

CNS abnormalities including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit; cardiovascular abnormalities; thymus gland abnormalities; parathyroid hormone deficiencies. In some cases death has occurred with certain of the abnormalities noted.

Line drawing represents the possible abnormalities of the low-set, deformed, or absent ears; wide-set eyes; depressed bridge of nose; enlarged head; and small chin.



Line drawing represents the possible abnormalities of the brain, heart, and thymus gland that may occur.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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THE iPLEDGE PROGRAM

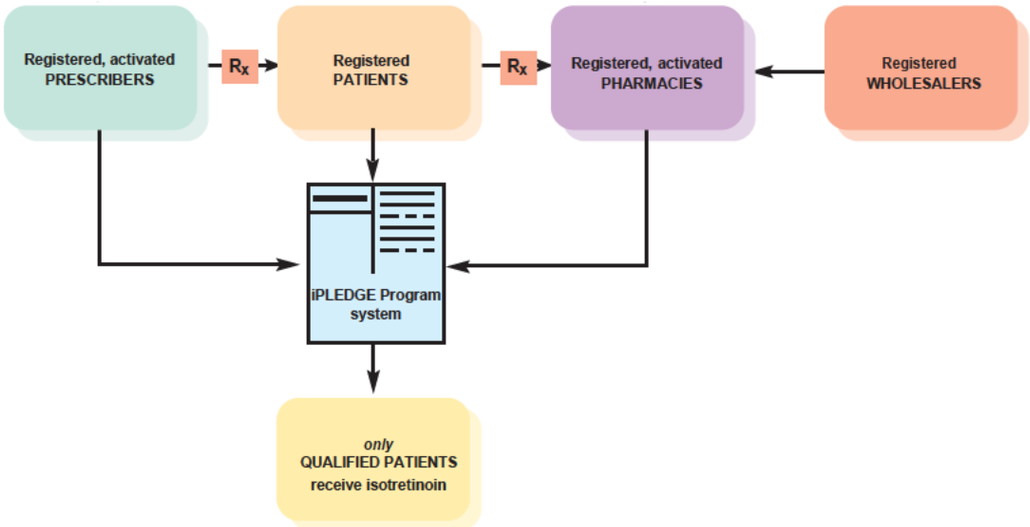
Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE. The iPLEDGE Program is a single, shared Risk Evaluation and Mitigation Strategy (REMS) program for prescribing and dispensing all isotretinoin products (brand and generic products) and includes a pregnancy registry.

Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see PRECAUTIONS).

The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions.

The iPLEDGE Program employs a computer-based risk management system that uses verifiable, trackable links between prescriber, patient, pharmacy, and wholesaler to control prescribing, using, dispensing, and distribution of isotretinoin.

The trackable links of the iPLEDGE Program



Key Features Of The iPLEDGE Program

The iPLEDGE Program has specific requirements for prescribers, patients, pharmacists, and wholesalers. Here is an overview:

- The iPLEDGE system tracks and verifies critical program elements that control access to isotretinoin.
- Only prescribers registered with and activated in the iPLEDGE Program can prescribe isotretinoin.
- Prescribers or their office designee must enter required information (pregnancy test results, 2 forms of contraception used, confirmation of patient counseling) in the iPLEDGE system for patients to be qualified to receive a prescription after the patient correctly answers a few comprehension questions..
- Prescribers must document that all patients—and specifically females of reproductive potential—meet the requirements in the iPLEDGE Program.

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- Only patients who are registered by prescribers in the iPLEDGE Program can receive isotretinoin.
- Females of reproductive potential must enter required information (2 forms of contraception used, answer questions on program requirements) in the iPLEDGE Program system in order to be qualified to receive a prescription.
- Only pharmacies registered with and activated in the iPLEDGE Program can dispense isotretinoin.
- Pharmacists must access the iPLEDGE Program system to receive authorization to fill and dispense every isotretinoin prescription.
- Telephone, fax, and electronic transmission (e.g., e-mail) prescriptions are permitted in the iPLEDGE Program.
- Manufacturers will only ship isotretinoin to iPLEDGE Program-registered entities (e.g., direct vendor pharmacies, wholesalers).
- Wholesalers must register annually in the iPLEDGE Program. A registered wholesaler may distribute only FDA-approved isotretinoin product.
- Only wholesalers registered with the iPLEDGE Program can distribute isotretinoin.
- Registered wholesalers can only ship isotretinoin to wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer or pharmacies licensed in the US and registered and activated in the iPLEDGE Program.

Non-Compliance Action Policy (NCAP)

The Non-Compliance Action Policy was implemented to monitor compliance, address deviations, and institute appropriate corrective actions to improve minimization of drug exposure during pregnancy and compliance with elements to assure safe use under the iPLEDGE Program. The NCAP sets forth the principles by which Non-Compliance by iPLEDGE Program stakeholders will be evaluated. The NCAP can be found on the iPLEDGE Program website at www.ipledgeprogram.com

KEY INFORMATION FOR PRESCRIBERS

Prescribers need to follow the key points of the iPLEDGE Program. These points are explained in detail in *The Guide To Best Practices For the iPLEDGE Program*. The key areas the prescriber must understand include:

The Non-Compliance Action Policy (NCAP)

- The iPLEDGE Program educational materials for prescribers and patients
- Activation in the iPLEDGE Program automated system
- Prescriber steps required "Before," "During," and "After" treatment with isotretinoin
- Specific program criteria and procedures for females of reproductive potential
- Education for all patients about isotretinoin and the iPLEDGE Program requirements
- Patient registration
- The initial and monthly procedures for prescribing isotretinoin and information on the requirements for pharmacists
- Information on what to do in the event of a pregnancy
- Prescriber delegates and office staff designees

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS .**

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THE iPLEDGE WEB SITE AND PHONE SYSTEM

The prescriber can access the iPLEDGE Program system via the program web site and automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The automated system is used to:

- Activate registration
- Register patients
- Confirm patient counseling monthly for all patients for each prescription
- Enter monthly pregnancy test results and contraception information for females of reproductive potential. **The patient cannot answer her monthly questions until the prescriber has entered the pregnancy test results in the iPLEDGE Program system.**
- Track the current status of a patient.
- Order additional copies of *The Guide To Best Practices For the iPLEDGE Program* and of patient and professional educational materials
- Manage delegates and designate office staff
- Find a participating pharmacy
- Enter and make changes to patient name, address, phone number and date of birth.
- Edit prescriber name, specialty, address, phone and fax numbers, e-mail address and preferred method of communication (US Mail or e-mail)

Logging in to either the web site or phone system requires a username and password, which are supplied upon registration.

To review and order materials

You can order additional program materials using either the web site or the phone system as follows:

1. After logging on to the web site, there are two ways to order materials:
   a. Using the navigation menu on the left side of the page, select the "Order Materials" button.

      OR

   b. Using the navigation menu on the left side of the page choose "Prescriber Information". In the "View Information Online" section, Select "To Order Educational Materials, please click here".
2. In the phone system, log in and select the option to "Request Program Information."

Materials will be shipped via ground delivery, and should arrive in 5 to 7 business days. The prescriber address in the iPLEDGE Program at the time of the order will be used for the shipping destination. This address can be changed by the user as needed to direct shipments to specific desired locations.

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PROGRAM MATERIALS

The iPLEDGE Program provides educational materials for prescribers and patients. There is also a guide for pharmacists.

Prescriber Materials

It is important that the prescriber reviews the materials in the educational kit.

1. *The Guide To Best Practices For the iPLEDGE Program* describes the requirements of the iPLEDGE Program for prescribers and for male and female patients.
2. *The iPLEDGE Program Prescriber Contraception Counseling Guide* is an overview of the effective forms of contraception and is a companion to the patient *iPLEDGE Program Birth Control Workbook*.
3. The brochure *Recognizing Psychiatric Disorders In Adolescents And Young Adults* contains important information about depression, suicide, and psychiatric assessment and referral of your patients.

Additional materials

Additional resource materials can be viewed on the iPLEDGE Program web site. These include:

- Isotretinoin Medication Guide
- Isotretinoin Package Inserts
- Prescribing Checklists
- Isotretinoin Contraception Referral Form
- Prescriber Activation Instructions
- Instructions for Registering and Managing Office Staff Designees
- Patient and Prescriber Flowcharts
- FAQ's (Frequently Asked Questions)

Patient Materials

The prescriber distributes *The iPLEDGE Program Patient Introductory Brochure* to patients considering taking isotretinoin. A patient educational kit, which provides information about the iPLEDGE Program requirements, should be given to the patient when they are registered in the iPLEDGE Program.

All kits include:

- The appropriate patient guide—*The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant or The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant*

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

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- The Patient Information/Informed Consent (for all patients) form
- The patient ID card and number

Additionally, the kit for females of reproductive potential includes:

- *The iPLEDGE Program Birth Control Workbook*. This provides in-depth information about effective forms of contraception with iPLEDGE and their optimal use.
- *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. This includes the form to refer your patient to a contraception expert for counseling and a guide for the counselor about the requirements of the iPLEDGE Program.
- The Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.

Educational Video

The prescriber educational kit also includes educational materials for patients with two videos: ***Be Prepared, Be Protected*** and ***Be Aware: The Risk of Pregnancy While on Isotretinoin.*** These describe the kind of birth defects that may happen if a woman takes any amount of isotretinoin while she is pregnant and also review reasons for contraception failure.

ACTIVATING REGISTRATION

iPLEDGE registration must be activated in the iPLEDGE Program system before a prescriber can prescribe isotretinoin. Activation must occur annually.

The iPLEDGE Program system will report the expiration date of the prescriber's activation. To retrieve this information, the prescriber:

- On the web site, logs in and chooses "My Program Status" on the left navigation
- In the phone system, logs in and selects the option to hear "Program Status"

The prescriber should review *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide* to understand the program. Activation requires the prescriber to attest to the following statements in the iPLEDGE Program system:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I know the risk factors for unplanned pregnancy and the effective measures for avoidance of unplanned pregnancy.
- I have the expertise to provide the patient with detailed pregnancy prevention counseling or I will refer her to an expert for such counseling, reimbursed by the manufacturer.
- I will comply with the iPLEDGE Program requirements described in the booklets entitled *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide*.

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- Before beginning treatment of females of reproductive potential with isotretinoin, and on a monthly basis, the patient will be counseled to avoid pregnancy by using 2 forms of contraception simultaneously and continuously 1 month before, during, and 1 month after isotretinoin therapy, unless the patient commits to continuous abstinence.
- I will not prescribe isotretinoin to any female of reproductive potential until verifying she has a negative screening pregnancy test and monthly negative CLIA-certified (Clinical Laboratory Improvement Amendment) pregnancy tests. Patients should have a pregnancy test at the completion of the entire course of isotretinoin and another pregnancy test 1 month later.
- I will report any pregnancy case that I become aware of while the female patient is on isotretinoin or 1 month after the last dose to the pregnancy registry.

Procedures For Activating In The iPLEDGE System

The prescriber can access the iPLEDGE Program system to activate registration via the web site, **www.ipledgeprogram.com**, or the automated phone system, **1-866-495-0654.** The web site is the faster and easier way to access the system. Identification in either system requires the username (DEA number or program-generated user-name) and password received with the registration materials. For information on the internet browsers compatible with the iPLEDGE Program web system, consult the FAQ's on the home page of the site, www.ipledgeprogram.com.

The system requires setting the prescriber's Date of Personal Significance. This is a date that the prescriber will be able to easily remember. It will be used to verify prescriber identity if needed by the iPLEDGE Program system or if a password is lost.

After initial activation, a prescriber must re-activate at least annually to remain active in the iPLEDGE Program. The iPLEDGE Program system will display the "Activate" button on the Prescriber home page when the activation for a prescriber is nearing expiration. However, a prescriber can re-activate at any time using the "Prescriber Activation" button on the left-hand navigation menu on all pages.

Using the web site

The prescriber:

1. Logs in by entering username (DEA number or program-generated username) and password.
   - The system will provide prompts to change the prescriber's password and set the prescriber's Date of Personal Significance.
2. On the Prescriber home page, select "Activate My Registration". **The system will provide prompts to complete the activation process.** If your current activation is nearing expiration, the Prescriber home page will prominently display a direct link to re-activate.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Using the phone system

The prescriber:

1. Logs in and follows the prompts.
   - The system will provide prompts to change the prescriber's password and set the prescriber's Date of Personal Significance.
2. Selects the option to "Activate Your Registration." The system will provide prompts to complete the activation process.

OVERVIEW: PROGRAM REQUIREMENTS

The iPLEDGE Program has specific requirements for prescribers, patients, and pharmacists. One of the prescriber's main responsibilities is knowing and educating patients about these requirements.

Prescribers are responsible for registering every patient, who meets the program requirements, in the iPLEDGE Program via the automated system. They are responsible for educating patients about the side effects of isotretinoin and the high risk of birth defects for females of reproductive potential while taking the drug. As part of this process, they are also responsible for counseling patients about the monthly steps they must follow to receive isotretinoin.

Prescribers can only write a patient's prescription for isotretinoin for up to a maximum of a 30-day supply. Patients must plan for monthly appointments to receive their prescriptions. At each of these appointments, the prescriber must counsel the patient about the iPLEDGE Program requirements and then confirm via the iPLEDGE automated system that this counseling occurred.

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient, as follows:

Female patients who can get pregnant…	Male patients and female patients who cannot get pregnant…
The prescription window is 7 days, and starts on the date that the urine or blood sample is taken for a pregnancy test. This date is counted as DAY 1. To determine the end date of their 7-day prescription window, these patients should add 6 days to the date of the blood or urine sample being taken.	The prescription window is 30 days, and starts on the date the prescriber enters as the date of the office visit. This date is counted as DAY 1. To determine the end date of their 30-day prescription window, these patients should add 29 days to the date of their office visit.

After 11:59 p.m. Eastern Time on the last day of the prescription window, the patient can no longer fill and pick up their prescription, and must start the process over to get a new prescription window*

*There are generally no restrictions regarding the timing of office visits. One notable exception is that females of reproductive potential who do not obtain their first month of therapy prescription in their first 7-day prescription window, must wait at least 19 days from their most recent pregnancy test until getting their next pregnancy test. This is based on the requirement that the most recent pregnancy test prior to beginning therapy must be conducted in the first 5 days of her menstrual cycle.

There are different program requirements for male patients and females of non-reproductive potential and for females of reproductive potential..

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The prescriber must determine if a patient is a female of reproductive potential (see page 18) and document that she meets the specific requirements of the program. These include taking pregnancy tests and using 2 forms of birth control consistently. Both of these requirements must be followed before, during, and after treatment.

To receive monthly prescriptions, a female of reproductive potential must also answer questions in the iPLEDGE Program system about the program requirements and pregnancy prevention. **Answering these questions can only take place after the prescriber has confirmed counseling, and entered the pregnancy test result and the patient's 2 forms of contraception (or reliance on abstinence) into the system.** In addition to answering the questions, the patient must also enter the 2 forms of birth control she is using (or indicate that she is relying on abstinence).

The pregnancy test can be obtained prior to, at the time of, or after the office visit. **However, the 7-day prescription window will begin with the date that the specimen draw was performed.**

These are the criteria the system uses to authorize a pharmacy to fill and dispense a prescription.

The Guide To Best Practices For the iPLEDGE Program includes a checklist of steps to follow before, during, and after patient treatment. *(see page 15)*

Below are the main requirements for patients and pharmacists.

Requirements For All Patients

To receive isotretinoin, all patients must meet all of the following conditions:

1. ***Must*** be registered with the iPLEDGE Program by the prescriber
2. ***Must*** understand that severe birth defects can occur with the use of isotretinoin by female patients
3. ***Must*** be reliable in understanding and carrying out instructions
4. ***Must*** sign a Patient Information/Informed Consent (for all patients) form that contains warnings about the potential risks associated with isotretinoin
5. ***Must*** obtain the prescription within the prescription window defined as follows:
   - Male patients and female patients who cannot get pregnant must obtain their prescription within the 30-day prescription window, counting the office visit as DAY 1.
   - Female patients who can get pregnant must obtain their prescription within 7 days of their pregnancy test, which is determined by the date of the blood draw or urine sample used in the test. The pregnancy test can be obtained before, during or after the office visit.

6. ***Must*** not donate blood while on isotretinoin and for 1 month after treatment has ended

7. ***Must*** not share isotretinoin with anyone, even someone who has similar symptoms

All patients should understand that refills are not allowed. Patients can only receive a maximum of a 30-day supply of isotretinoin per prescription. For each prescription, continuation of therapy requires the patient to satisfy the iPLEDGE Program requirements to obtain a new prescription. The prescriber must also counsel the patient monthly about the iPLEDGE Program requirements and then confirm via the iPLEDGE Program system that this counseling occurred.

Females of reproductive potential must:

- Have an initial pregnancy test, which may be performed in the prescriber's office
- Be counseled on contraception requirements
- Use 2 forms of contraception together for sexual intercourse for 1 month before, during, and for 1 month after treatment with isotretinoin
- There is a 30-day mandatory waiting period during which females of reproductive potential must be using both chosen forms of birth control simultaneously before they are eligible to begin treatment with isotretinoin.
- Have a second pregnancy test within the first 5 days of the menstrual cycle, performed in a CLIA-certified laboratory, after being on 2 effective forms of contraception for 1 month and before starting isotretinoin therapy.* This second pregnancy test must be at least 19 days after the initial pregnancy test.
- Fulfill monthly requirements before receiving each prescription:
  - Have a serum or urine pregnancy test performed in a CLIA-certified laboratory*
  - Access the system to answer questions about the iPLEDGE Program requirements and pregnancy prevention
  - Enter into the iPLEDGE Program system the 2 forms of contraception being used
- Have a pregnancy test after their last dose, performed in a CLIA-certified laboratory
- Continue using 2 forms of contraception for 1 month after their last dose
- Have a pregnancy test 1 month after their last dose

About the patient questions

Prior to being able to obtain a prescription, females of reproductive potential ***must*** answer questions about the iPLEDGE Program and pregnancy prevention. **These questions must be answered after their prescriber has confirmed counseling, entered pregnancy test results and 2 contraceptive methods (or reliance upon abstinence) into the iPLEDGE Program system, but before the 7-day prescription window for their prescription expires.** Patients answer these questions via the web site or phone system. (Access information is provided in the patient guide.) The patient may use her patient guide and *The iPLEDGE Program Birth Control Workbook* to help with the answers.

* For timing information about monthly pregnancy tests, see number 1 on page 19 under "Qualification criteria for females of reproductive potential"

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The system provides questions in several specific categories and correct answers for those questions, with references to the appropriate patient education material. A replacement question in the same category is provided for an incorrectly answered question.

If a patient misses a replacement question, the iPLEDGE Program system will direct her to review her materials and try again at a later time. She may also contact her prescriber so that her program education and counseling can be reinforced. The patient should also review her educational materials and then answer the question again.

Requirements For Pharmacists

- Isotretinoin can only be obtained from pharmacies registered with and activated in the iPLEDGE Program.
- Registered and activated pharmacies can obtain isotretinoin only from wholesalers registered with the iPLEDGE Program.
- **The dispensing pharmacist must obtain authorization and a Risk Management Authorization (RMA) number** before filling and dispensing prescriptions.
- **Upon receiving authorization, the dispensing pharmacist can fill and dispense a prescription** for a maximum 30-day supply of isotretinoin.
- **Upon authorization, the iPLEDGE Program system** provides the RMA number to the dispensing pharmacist. The pharmacist should document the RMA number.
- **Upon authorization, the iPLEDGE Program system** provides a "**Do Not Dispense To Patient After**" date to the dispensing pharmacist. This date is calculated as 30 days from the office visit for male patients and females of non-reproductive potential, or 7 days from the pregnancy test date for females of reproductive potential. The pharmacist should record this date on the prescription bag sticker.
- **The iPLEDGE Program system** only authorizes filling and dispensing prescriptions when patients have met the qualification criteria in the system.
- **Prescriptions** that are more than 30 days beyond the date of the office visit (for male patients and females of non-reproductive potential) or more than 7 days beyond the pregnancy test date (for females of reproductive potential), will not be authorized by the iPLEDGE Program system.
- Prescriptions must be obtained no later than the "Do Not Dispense To Patient After" date, and if not obtained, then the RMA must be reversed in the iPLEDGE Program system and the product returned to inventory.
- **No automatic refills** are permitted.
- **Isotretinoin** comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.
- An isotretinoin Medication Guide must be given to the patient each time isotretinoin is dispensed, as required by law.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

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Pharmacy Information

Patients can only obtain isotretinoin prescriptions from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com**, provides a database of registered pharmacies. Patients and prescribers can access this information by logging in and choosing the "Find a Participating Pharmacy" button on their home page.

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

iPLEDGE PROGRAM PRESCRIBING CHECKLISTS

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient, as follows:

Female patients who can get pregnant…	Male patients and female patients who cannot get pregnant…
The prescription window is 7 days, and starts on the date that the urine or blood sample is taken for a pregnancy test. This date is counted as DAY 1. To determine the end date of their 7-day prescription window, these patients should add 6 days to the date of the blood or urine sample being taken.	The prescription window is 30 days, and starts on the date the prescriber enters as the date of the office visit. This date is counted as DAY 1. To determine the end date of their 30-day prescription window, these patients should add 29 days to the date of their office visit.

After 11:59 p.m. Eastern Time on the last day of the prescription window, the patient can no longer fill and pick up their prescription, and must start the process over to get a new prescription window*

*There are generally no restrictions regarding the timing of office visits. One notable exception is that females of reproductive potential who do not obtain their first month of therapy prescription in their first 7-day prescription window, must wait at least 19 days from their most recent pregnancy test until getting their next pregnancy test. This is based on the requirement that the most recent pregnancy test prior to beginning therapy must be conducted in the first 5 days of her menstrual cycle.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.** 6/4/12 1 29 PM

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Females Of Reproductive Potential

Before

PLANNING

- ❑ **Plan** for office visits, counseling, pregnancy testing.
- ❑ **Educate** about isotretinoin and the contraception requirements of the iPLEDGE Program.
- ❑ **Screen** with serum or urine pregnancy test, which may be performed in the prescriber's office: must be negative for patient to enter the iPLEDGE Program system.
- ❑ **Obtain** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Register** patient in the iPLEDGE Program system and provide patient with an educational kit, which includes the Patient ID number on perforated, removable cards.

COUNSEL ON CONTRACEPTION

- ❑ Counsel patient in office or refer to healthcare professional with expertise in contraception. Please see page 22 for information on referring for contraception counseling.
- ❑ **Counsel** patient that she must use 2 effective forms of contraception simultaneously for at least 1 month before starting therapy. There is a 30-day mandatory waiting period during which she must be using both chosen forms of birth control before she is eligible to begin treatment with isotretinoin.
- ❑ **Inform** patient about confidential iPLEDGE Program Pregnancy Registry.

PRESCRIBE

- ❑ Verify female patient qualification criteria.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory:
  - During the first 5 days of the menstrual cycle, OR
  - For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month. Please refer to the section on. "Qualification criteria for females of reproductive potential" (*see page 19*) for details on the timing of this test.
- ❑ **Obtain** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system within the 7-day prescription window, counting the date of specimen collection for the pregnancy test as DAY 1. Your patient will not be able to answer her comprehension questions and then obtain her prescription until you have completed this task.

During
(at each monthly visit)

- ❑ **Counsel** patient on contraception adherence.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system within the 7-day prescription window, counting the date of specimen collection for the pregnancy test as DAY 1. Your patient will not be able to answer her comprehension questions and then obtain her prescription until you have completed this task.

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After

AFTER THE LAST DOSE

- ❑ **Counsel** patient on contraception adherence for 30 more days.
- ❑ **Counsel** patient not to give blood for at least 1 month after the last dose.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory after the last dose.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system.
  - If you do not enter the results of the pregnancy test at the conclusion of therapy, the patient will be classified as Lost to Follow Up, and both you and the patient may be contacted for additional information.

1 MONTH AFTER THE LAST DOSE

- ❑ **Order** a pregnancy test using a CLIA-certified laboratory.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system.
  - If you do not enter the results of the pregnancy test 1 month after the conclusion of therapy, the patient will be classified as Lost to Follow Up, and both you and the patient may be contacted for additional information.

Refer to page 27 for information about reporting pregnancies to the confidential iPLEDGE Program Pregnancy Registry.

Male Patients And Female Patients Who Cannot Get Pregnant

Before

PLANNING

- ❑ **Plan** for monthly office visits.
- ❑ **Educate** patients about isotretinoin and the iPLEDGE Program.
- ❑ **Obtain** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Register** patients in the iPLEDGE Program system and provide patient with an educational kit, which includes the Patient ID number on perforated, removable cards.

PRESCRIBE

- ❑ **Confirm** patient counseling about program requirements in the iPLEDGE Program system within the 30-day prescription window, counting the patient's office visit as DAY 1. The patient will not be able to obtain his/her prescription until you have completed this task.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.

During
(at each monthly visit)

- ❑ **Counsel** patient on program adherence.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system within the 30-day prescription window, counting the patient's office visit as DAY 1. The patient will not be able to obtain his/her prescription until you have completed this task.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.

After

AFTER THE LAST DOSE

- ❑ **Counsel** patient not to give blood for at least 1 month after the last dose.

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DETERMINE REPRODUCTIVE POTENTIAL OF FEMALE PATIENTS

Qualification Criteria

The prescriber must determine if a female is of reproductive potential before enrolling her in the iPLEDGE Program. The definition of a female of reproductive potential is a nonmenopausal female who has not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure. This definition includes a young woman who has not yet started menstruating.

- A woman who has had a tubal sterilization is considered a female of reproductive potential in the iPLEDGE Program.

Definition of menopause

Menopause can be assumed to have occurred in a woman when there is either:

1. Appropriate medical documentation of prior complete bilateral oophorectomy (i.e., surgical removal of the ovaries, resulting in "surgical menopause" and occurring at the age at which the procedure was performed), OR

2. Permanent cessation of previously occurring menses as a result of ovarian failure with documentation of **hormonal deficiency** by a certified healthcare provider (i.e., "spontaneous menopause," which occurs in the United States at a mean age of 51.5 years).

Hormonal deficiency should be properly documented in the case of suspected spontaneous menopause as follows:

1. If age >54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed;

2. If age <54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

Screen patients

Data support that there are key issues in identifying female patients for treatment with isotretinoin.

The prescriber should:

1. Identify patients whose acne could be effectively managed without isotretinoin and avoid prescribing it for such patients
2. Identify those who are already pregnant when considering isotretinoin
3. Identify those who may not be reliable in avoiding pregnancy for the required period before, during, and after therapy

The patient should understand that, ultimately, it is her responsibility to avoid exposing an unborn baby to isotretinoin. The patient must understand the critical responsibility she assumes in electing to undertake therapy with isotretinoin and that any method of birth control, apart from complete abstinence, can fail.

The prescriber must verify that each individual patient receives adequate counseling about all her pregnancy prevention options (including abstinence) and that she knows how to select and use 2 separate, effective contraceptive methods.

Qualification criteria for females of reproductive potential

Once the prescriber decides to pursue qualification of the patient, a female of reproductive potential must follow these steps.

1. Before the patient can begin isotretinoin therapy, there is a 30-day wait period where the patient must be on two forms of birth control simultaneously. Additionally, she will need to have 2 negative pregnancy tests. Femalesof reproductive potential must have had 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL before receiving the initial isotretinoin prescription. The first test (a screening test) is obtained by the prescriber when the decision is made to pursue qualification of the patient for isotretinoin. The second pregnancy test (a confirmation test) must be done in a CLIA-certified laboratory. The interval between the 2 tests must be at least 19 days.
   - For patients with regular menstrual cycles, the second pregnancy test must be done during the first 5 days of the menstrual period, immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - The patient must be using her two forms of contraception for at least 30 days prior to beginning therapy on isotretinoin, and her second pregnancy test must occur after this 30-day period is complete.
2. The patient must sign a Patient Information/Informed Consent (for all patients) form and a Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.

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3. The patient must select and commit to use 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. Patients must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy. Counseling about contraception and behaviors associated with an increased risk of pregnancy must be repeated on a monthly basis prior to issuing each prescription.

Monthly requirements

Each month of therapy, patients must have a negative result from a urine or serum pregnancy test. A pregnancy test must be repeated each month, in a CLIA-certified laboratory, prior to the female patient receiving each prescription. A pregnancy test must also be ordered at the end of therapy (after the last dose), and 1 month after the last dose. If the results of the pregnancy tests at the conclusion of therapy, and the pregnancy test 1 month after the conclusion of therapy, are not entered into the iPLEDGE system, the patient will be classified as Lost to Follow Up, and both the prescriber and the patient will be contacted for additional information. The iPLEDGE Program also requires monthly counseling about contraception and behaviors associated with an increased risk of pregnancy.

In addition to their required doctor appointments, females of reproductive potential each month must also enter their 2 effective forms of contraception in the iPLEDGE Program system and answer questions about the iPLEDGE Program and pregnancy prevention.

Effective Forms Of Contraception

Effective forms of contraception include both primary and secondary forms of contraception.

Primary forms	Secondary forms
• Tubal sterilization • Partner's vasectomy • Intrauterine device • Hormonal (combination oral contraceptives, transdermal patch, injectables, implantables, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier forms (used with or without permicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

Unacceptable Forms Of Contraception Include:

- Progesterone-only "mini-pills,"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield‡

Abstinence

For this program, all females of reproductive potential must fully commit to pregnancy prevention. Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE Program who are or have been sexually active. Abstinence may be appropriate when it is a lifestyle choice (e.g., religious practice) and not just a social circumstance (e.g., not having a current partner). If, after counseling, a sexually active patient chooses abstinence without contraception, she must understand that isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program. All females of reproductive potential must receive contraception counseling.

Contraception Counseling

The prescriber must ensure that each individual patient receives adequate counseling about all her pregnancy prevention options (including abstinence) and that she knows how to select and use 2 separate, iPLEDGE Program-effective forms of contraception that will give her the lowest failure rate.

The patient must understand the critical responsibility she assumes in electing to undertake therapy with isotretinoin and that any form of birth control, apart from complete abstinence, can fail. All females of reproductive potential must read the patient *iPLEDGE Program Birth Control Workbook*.

Reinforce the message

Counseling about contraception must be repeated on a monthly basis. Approximately 30% of female patients said they did not use 2 forms of contraception, even when knowing the risks and having consented.[2] Active counseling is one of the best tools toward getting patient compliance.

When counseling patients on contraception, the prescriber should refer to *The iPLEDGE Program Prescriber Contraception Counseling Guide*, which contains an overview of issues in contraception and the effective forms of contraception in the iPLEDGE Program. It is a companion to the patient *iPLEDGE Program Birth Control Workbook*.

It is especially important to assess the patient's ability to understand her responsibilities and instructions, and to reinforce these instructions at every clinical visit. It is very important to be able to make a careful assessment of a female patient's reproductive history, contraceptive knowledge, and previous use of contraception forms. This assessment and contraceptive education should continue throughout isotretinoin treatment.

*Ortho Micronor is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception. See page 20.

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Referral for contraception counseling

Before beginning treatment, the prescriber or patient may choose referral to a healthcare professional with expertise in pregnancy prevention. The makers of isotretinoin will reimburse one visit for contraception counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The form is in the booklet; the guide outlines the contraception requirements and the effective forms of contraception of the iPLEDGE Program for the birth control expert.

The referral form should be taken to the contraception counselor by the patient or sent in advance. The form instructs the counselor to fill in the appropriate information and return it to the prescriber with the patient's contraception choices to enter into the iPLEDGE Program system. The reverse side of the form has information for the counselor on the reimbursement process.

Referring to a gynecologist

The prescriber may want to specifically refer a patient to a gynecologist for:

- An examination prior to starting oral contraceptive agents or a hormonal transdermal patch
- Insertion of an IUD or hormonal vaginal ring
- Fitting a diaphragm or a cervical cap
- More detailed explanation of contraception options

The prescriber should also ask for gynecologic consultation under the following circumstances:

- The patient's history is suggestive of polycystic ovary syndrome (Stein-Leventhal syndrome). In addition to acne she may have:
  - Excessive facial hair growth (common when acne is present)
  - Obesity
  - Amenorrhea (no menstrual period) or irregular, heavy bleeding
  - Anovulation
- The patient has irregular menses, possibly related to pregnancy; an eating disorder; or endometriosis. It is important that the prescriber weighs the patient if there is suspicion of a potential eating disorder. Patients with eating disorders may:
  - Not admit to the problem
  - Be very underweight
- There are indications of sexual abuse found during the physical examination or counseling session.
- There is history or are symptoms of sexually transmitted infection.

Confidential birth control information

The iPLEDGE Program has automated confidential birth control information that patients can use 24 hours a day, 7 days a week. Patients can call the program's toll-free number **1-866-495-0654** and obtain information on a variety of subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

This is also a good option for patients who are vision impaired. Patients are always referred to their prescribers for additional information and clarification.

iPLEDGE PROGRAM PRESCRIBING INFORMATION

Register Patients In The iPLEDGE Program System

Patients may be registered in the iPLEDGE Program system either via the web site or phone system after obtaining the Patient Information/Informed Consent (for all patients) form and providing the patient with an ID number and ID card. The process is faster and easier using the web site.

On the web site, the prescriber logs in and chooses "Register New Patient." In the phone system, the prescriber logs in and selects the option to "Register a New Patient."

The system will request this specific patient information:

- Patient ID number
- Patient first and last name and middle initial
- Home address
- Phone number
- Date of birth
- Gender
- Last four digits of the Social Security number
- Female of reproductive potential (Yes or No)
- Screening pregnancy test date and results

ID number and ID card

The ID number and perforated ID cards are provided with the patient education materials. It is important that patients do not lose the cards. Prescribers should keep a record of the patient's number.

- All patients need the ID number and ID card to obtain their prescriptions, and to access the web site or automated phone line.
- Females of reproductive potential will need their ID number to access the iPLEDGE Program system to answer questions about the iPLEDGE Program and preventing pregnancy.

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Informed consents

Patients will need to sign the following consent forms to be in the iPLEDGE Program.

- Patient Information/Informed Consent (for all patients)
- Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)

For females of reproductive potential, signing the Patient Information/ Informed Consent About Birth Defects (for female patients who can get pregnant) form means the following.

- They understand the teratogenic risks of isotretinoin.
- They agree to follow the contraception requirements of the iPLEDGE Program before, during, and for 1 month after their treatment with isotretinoin.

Prescriptions: System Requirements

Before a patient can obtain a prescription for isotretinoin at a registered pharmacy, the iPLEDGE Program system requires that the information below be entered into the system and the timing criteria for filling and dispensing a prescription be met. This is the information that the system will use to authorize filling a prescription and to provide the Risk Management Authorization (RMA) number and the **"Do Not Dispense To Patient After"** date.

All patients

Prescriber confirms that:

- The patient is registered with the iPLEDGE Program
- The patient was counseled on the iPLEDGE Program requirements

Females of reproductive potential

Prior to the patient obtaining each prescription, the prescriber must access the iPLEDGE Program system to:

- Confirm that the patient was counseled about isotretinoin and the iPLEDGE Program contraception requirements
- Enter the 2 forms of contraception that the patient is using
- Enter pregnancy result into the iPLEDGE Program system, within the 7-day prescription window, counting the date of blood draw or urine sample as DAY 1
- **The patient cannot answer her monthly questions and get a prescription filled until after these activities are completed by the prescriber.**

A positive pregnancy test prevents the prescription from being filled.

Patient must access the iPLEDGE Program system after the prescriber has entered the pregnancy test results to:

- Correctly answer the questions about the iPLEDGE Program and pregnancy prevention
- Enter the 2 forms of contraception she is using

The primary form of contraception reported by both the prescriber and the patient must match.

Timing criteria for the prescription to be obtained from the Pharmacy

- All patients must obtain their prescriptions as follows:
  - For male and female patients who cannot get pregnant, prescriptions must be obtained within the 30-day prescription window, counting the office visit as DAY 1
  - For female patients who can get pregnant, prescriptions must be obtained within the 7-day prescription window counting the day of the blood draw or urine sample as DAY 1
- Patients will not be able to obtain prescriptions after their prescription window has expired.

The iPLEDGE Program system will automatically provide the pharmacist with a "Do Not Dispense To Patient After" date, which is the end of the prescription window. The pharmacist cannot fill or dispense the patient's prescription after that date.

After The Last Dose

All patients should be reminded not to give blood for at least 1 month after their last dose.

Females of reproductive potential must have pregnancy tests:

- After their last dose, and
- 1 month after their last dose
- If this information is not entered, the patient will be classified as Lost to Follow Up, and both the prescriber and the patient will be contacted for more information.

It is important to stress the need for continued contraception during the 1 month after the last dose. Patients also should be reminded to enter their 2 forms of contraception.

Post Treatment iPLEDGE Program Requirements

When a patient will no longer be taking isotretinoin, action is required by the prescriber to record specifics of the end of therapy. Specifically the following information is required by the iPLEDGE Program:

- If known when issuing the prescription, the prescriber will indicate that a prescription will be the last one for this patient. This will remind the prescriber of the patient requirements for post-treatment activity
- The prescriber **must** discontinue the patient within the iPLEDGE Program in one of the following ways:
  - On the website, select "Manage Patients", select the patient being discontinued, and choose the button for "Discontinue Patient".
  - On the phone system, select the option to "Manage Active Patients", and then select the option to "Complete or Discontinue Patient Treatment".

Please see accompanying complete product information, including boxed
CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

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- When discontinuing a patient through either the website or the phone system, the prescriber must enter the Date of Last Dose, and the reason why this patient will no longer be taking isotretinoin. This reason will be selected from a list presented by the iPLEDGE Program system, including Completed Therapy, Pregnancy, or Other. On the website, explanatory comments can also be provided, and may be required by the iPLEDGE Program system.
  - If the reason for discontinuation is related to an Adverse Event, please be as specific as possible in the comments entered in the iPLEDGE Program system.
- For females of reproductive potential, **a final pregnancy test is required at the date of last dose, and 30 days after date of last dose**.

If this information is not provided, and a patient has no activity in the iPLEDGE Program system for specific periods of time, the patient will be classified as Lost to Follow Up. If this occurs, prescribers and patients will be contacted by the iPLEDGE Program.

IN THE EVENT OF PREGNANCY

Counseling A Pregnant Patient

If a pregnancy does occur during isotretinoin treatment, isotretinoin must be discontinued immediately. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Reporting Pregnancy

The iPLEDGE Program Pregnancy Registry

The iPLEDGE Program Pregnancy Registry collects data on pregnancies that occur in female patients who become pregnant while taking isotretinoin or within 1 month of their last dose. Data from the registry are reported to the FDA and are used to assess the effectiveness of the iPLEDGE Program. The data are also used to evaluate further ways to reduce fetal exposure. Information gathered in the iPLEDGE Program Pregnancy Registry will be used for statistical purposes only and will be held in the strictest confidence.

The prescriber must report to the iPLEDGE Program Pregnancy Registry any pregnancy case that he/she becomes aware of while the female patient is on isotretinoin or 1 month after the last dose. Report a pregnancy by calling **1-866-495-0654**. Select the option to "Report a Pregnancy." All pregnancies should also be reported to the FDA via the MedWatch number: 1-800-FDA-1088

In female patients taking isotretinoin

1. Positive pregnancy test results should be entered in the iPLEDGE Program system. A Safety Surveillance Associate will call the prescriber.
2. A prescriber should call the iPLEDGE Program Call Center if he or she does not have a pregnancy test result but thinks the patient is pregnant.

In partners of males being treated with isotretinoin

If the prescriber becomes aware of a pregnancy in the partner of a male patient taking isotretinoin, the prescriber should report this pregnancy to the iPLEDGE Program Pregnancy Registry. The information will be forwarded to the manufacturer of the specific isotretinoin product for follow-up.

Males And Birth Defects

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.[3]

Isotretinoin also has not been shown to affect a male's ability to father children. Studies did not show effects on sperm count, how sperm look, or how well they swim and move. (For more information, see page 3.)

DELEGATES AND OFFICE STAFF

The iPLEDGE Program allows the prescriber to delegate patient management to other prescribers registered with the iPLEDGE Program (these are known as delegates) and to designate office staff to assist with data entry (these are known as designees).

Delegating To Another Prescriber

The prescriber must first add the name and required information for delegates into the iPLEDGE Program system. This function also allows the prescriber to define time frames for delegation and add or delete delegates.

To delegate to another prescriber

The prescriber:

1. Logs in to the web site, **www.ipledgeprogram.com**
2. Chooses "Manage Delegates/Designees" from the Prescriber home page
3. Chooses "Manage Delegates" from the Manage Delegates and Designees page
4. Enters the desired Delegate's iPLEDGE user ID, and the date, if any, when the delegate's role is to expire.
5. Chooses "Add" new delegate for first-time entry

Office Designees

The iPLEDGE Program provides a unique username and password to identified office staff to allow them to perform the following activities for the prescriber:

- Register patients and maintain the patient's information in the iPLEDGE Program
- Enter patient pregnancy results
- Confirm patient counseling
- Discontinue patients
- Manage delegates
- Check patient's program status

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The following functions are available only to a prescriber:

- Prescriber registration
- Prescriber activation—initial and renewal
- Serious Medical Reasons Exemption process

A prescriber may have one or more office staff designees. Designees may be associated with one or more prescribers.

- They need to register only once, regardless of the number of prescribers with whom they are associated.
- They may support all the registered prescribers in a multi-physician practice.
- They have rights for any patient delegated to an assigned prescriber.

Rights to perform the functions depend on the prescriber's rights and program status.

- If a prescriber is not activated in the iPLEDGE Program system, neither the prescriber nor the designated office staff can register a patient.

Designated office staff may access the automated system but must provide their own user ID and date of personal significance as identifiers.

The registered and activated prescriber is responsible for all information entered and activities performed in the iPLEDGE Program system by the office staff designee.

To designate office staff

The prescriber:

1. Logs in to the web site, **www.ipledgeprogram.com**
2. Chooses "Manage Delegates/Designees" from the Prescriber home page
3. Chooses "Register New Designee" from the Manage Delegates and Designees page
4. Fills in the required information on the registration online form
5. Selects "Save and Print" to save the new information and print the registration form

The office staff designee:

1. Signs and dates the completed form
2. Faxes or mails the completed form to the number or address provided

A username and password will be mailed to the designee upon completion of the registration process. The designee uses them:

- To log in to the automated system
- On the first log in, to reset password and choose a Date of Personal Significance as a system identifier

REFERENCES

1 Dai WS, Hsu MA, Itri LM Safety of pregnancy after discontinuation of isotretinoin *Arch Dermatol.* 1989;125:362-355

2 Mitchell, Allen A MD Isotretinoin Survey Allen A Mitchell, MD and Carla M Van Bennekom RN, MPH Slone Epidemiology Center at Boston University For presentation at FDA Advisory Committee Meeting: February 26-27, 2004

3 Centers for Disease Control and Prevention Birth defects: frequently asked questions Available at: http //www.cdc.gov/ncbddd/bd/faq1.htm#Whatisabirthdefect Accessed August 8, 2005

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

ACTIVATING DESIGNEE REGISTRATION

iPLEDGE registration must be activated in the iPLEDGE Program system before a designee can interact with the iPLEDGE Program. Activation must occur annually.

- The designee should review *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide* to understand the program. Activation requires the designee to attest to the following statements in the iPLEDGE Program system:
  - **Isotretinoin is teratogenic and must not be used by pregnant women.** The goals of the iPLEDGE program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. With these program goals in mind, iPLEDGE data is routinely analyzed to identify actions of non-compliance.

Information entered into the iPLEDGE system is considered part of the patient's medical record, and can be used to investigate suspected non-compliance. Verified non-compliance with regard to the iPLEDGE Program requirements can result in removal from the iPLEDGE Program.

Prescribers are responsible for all iPLEDGE activities performed by their Office Staff Designees. If an Office Staff Designee is found to be non-compliant with the iPLEDGE Program, resulting actions, including possible removal from the iPLEDGE Program, can include both the designee and the prescriber.

- **Verified Non-Compliance may be reported to the FDA.**

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For More Information About Isotretinoin

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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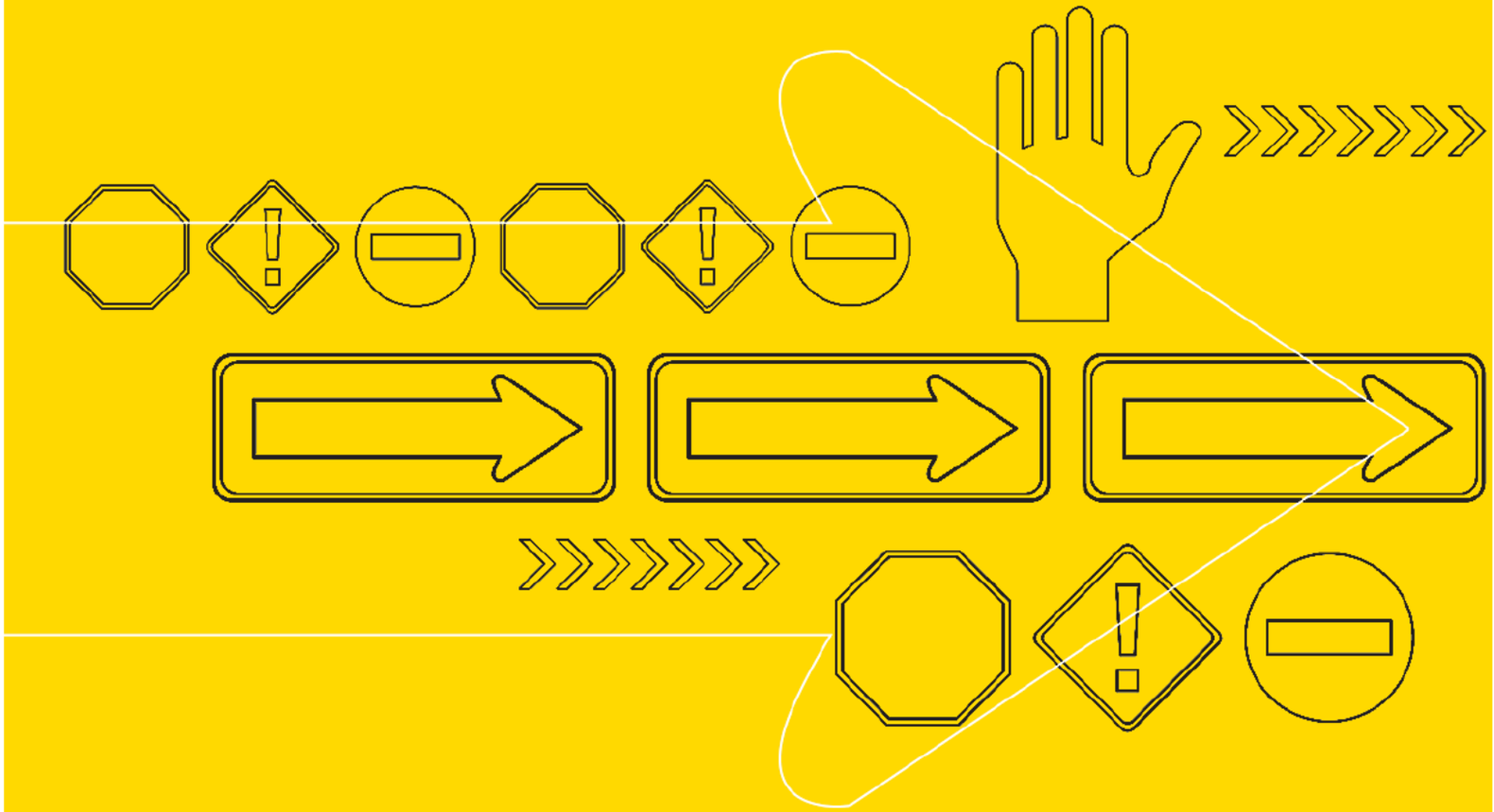

www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Committed to Pregnancy Prevention

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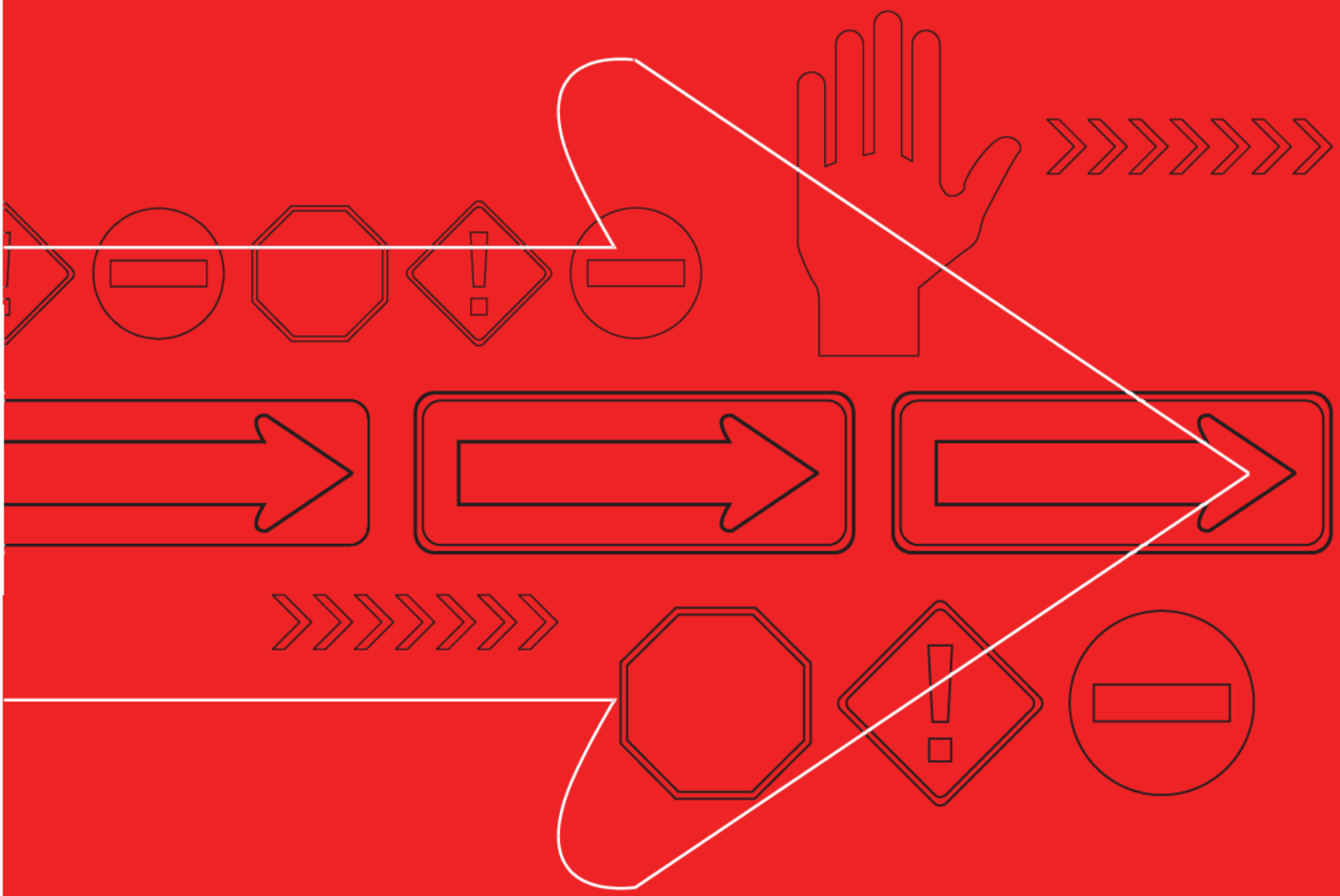

The information prescribers should communicate to patients to help prevent pregnancies during the course of isotretinoin therapy

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Most Recent Modification: July 2016

The iPLEDGE Program

Prescriber Contraception Counseling Guide

Helping patients prevent pregnancy

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INTRODUCTION

This *iPLEDGE Program Prescriber Contraception Counseling Guide* is intended to aid a prescriber who is not a gynecologist in counseling a female of reproductive potential who will be taking isotretinoin.

The patient must select and commit to using 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. Patients must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy.

It is strongly recommended that a patient use a primary form of contraception and is committed to using a second form as well, even if she says she will be abstinent for the entire required period. Isotretinoin is not recommended for sexually active females of reproductive potential whom you believe will not be able to maintain abstinence or will not use contraception, as the program requires.

The contraceptive that a patient selects can have a dramatic effect on her chance of becoming pregnant. A patient needs to select forms with low failure rates that she and/or her partner will use correctly each time they have intercourse. This *iPLEDGE Program Prescriber Contraception Counseling Guide* will help you enable the patient to select the 2 contraceptive forms that are consistent with the iPLEDGE Program guidelines *and* that she will use correctly and consistently.

Referral For Contraception Counseling

Before beginning treatment, the prescriber or patient may choose referral to a healthcare professional with expertise in pregnancy prevention. The makers of isotretinoin will reimburse 1 visit for contraception counseling. The patient educational kit contains the *iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the contraception requirements and the effective forms of contraception of the iPLEDGE Program for the birth control expert.

Contraception counseling is an important part of the patient choosing her two contraceptive forms. If practitioners are not comfortable providing this counseling, they are encouraged to take advantage of the opportunity to refer patients to a qualified counselor.

The referral form should be taken to the contraception counselor by the patient or sent in advance. The form instructs the counselor to fill in the appropriate information and return it to the prescriber with the patient's contraception choices to enter into the iPLEDGE Program system. The reverse side of the form has information for the counselor on the reimbursement process.

Counseling About Contraception

Please read this *iPLEDGE Program Prescriber Contraception Counseling Guide* completely before you begin your counseling session. The guide reviews the counseling goals and provides an overview of contraception choices from a pregnancy risk management context—necessary for female patients taking isotretinoin—information on obtaining a sexual and behavioral history (including additional guidance for interviewing an adolescent), and contraception reference materials.

Patients in the iPLEDGE Program receive *The iPLEDGE Program Birth Control Workbook*, which contains information on effective primary and secondary forms of contraception. It is not complete information on any of the forms, and the patient is encouraged to ask questions about specific forms or issues. The workbook has questions on such issues as medication adherence and lifestyle choices for the patient to think about in choosing contraception. Please review her responses with her.

COUNSELING GOALS

Ensure that the patient:

- Understands the risk of having a child with significant birth defects from exposure to isotretinoin.
- Understands the need for using 2 forms of contraception together consistently and correctly and knows when to contact her prescriber for emergency contraception (see page 27).
- Chooses the forms of contraception that will work best for her, that will provide her with the lowest practical failure rate, and that she and her partner will actually use. Adherence impacts the failure rate of hormonal combination oral contraceptives more strongly than other primary forms. (Please see "Hormonal Combination Oral Contraceptives As A Primary Form" on page 5.)
- Commits fully to not becoming pregnant and to using 2 forms of contraception simultaneously, consistently, and correctly. In previous isotretinoin risk management programs, patients understood the need for 2 forms of contraception; however, they did not comply, despite adequate information about the risk to the fetus. If, after counseling, the patient recognizes she will not be able to commit fully, encourage her to not take isotretinoin or do not prescribe.
- Is able and willing to maintain abstinence, if that is her choice after counseling. If a patient who has ever been sexually active chooses abstinence, and you believe that she will not be able to maintain abstinence and will not use contraception, encourage her to not take isotretinoin.

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Counseling younger teens

For younger teens, it is important to stress the following aspects of contraception for the iPLEDGE Program during counseling:

- The birth control forms that are effective as primary and secondary forms.
- Why it is important to use 2 forms of birth control. Younger teens may need more emphasis on this point to fully understand it and comply.
- The role of emergency contraception. Young teens may need more explanation from you about the need to take immediate action if they had unprotected sex. If she is under 18 years old, she may require a prescription or other assistance from a healthcare provider in order to use emergency contraception.

CONTRACEPTION REQUIREMENTS

Using 2 Forms Of Contraception Provides More Protection

Use of 2 forms of contraception simultaneously substantially reduces the chances that a female will become pregnant over the risk of pregnancy with either form alone.

In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin.[1] Because of this possibility, and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE Program requires the additional protection of a second form of contraception. The iPLEDGE Program requires the use of one "Primary Form" of contraception (Table 1) plus one "Secondary Form" of contraception (Table 2). Alternatively, the patient may select two primary forms of contraception.

Selecting An Effective Primary Form Of Contraception

Table 1 lists, by typical use failure rate, the primary forms of contraception acceptable in the iPLEDGE Program.

Table 1: Primary Forms of Contraception by Typical Use Failure Rate

	Percentage of Females Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Method	**Perfect Use**	**Typical Use**
Implantable Hormones	0.05%	0.05%
Partner's Vasectomy	0.10%	0.15%
Hormonal IUD (LNg 20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A)[b]	0.60%	0.80%
Hormonal Injectable (single)	0.20%	6.00%
Hormonal Transdermal Patch	0.30%	9.00%
Hormonal Vaginal Ring	0.30%	9.00%
Hormonal Combination Oral Contraceptives[b]	0.30%	9.00%

a Adapted from Trussell J Contraceptive failure in the United States Contraception 011;83:397–404 Available at: http: www ncbi nlm nih gov pmc articles PMC3638 09 Accessed September 9, 014

b The IUD Progesterone T and progestin-only "mini-pills" are not acceptable for the iPLEDGE program (See "Unacceptable Forms Of Contraception" on page 7)

The single most important decision in contraception for the iPLEDGE Program is selecting a primary form with a very low failure rate that the patient can and will use as perfectly as possible. Other important factors to consider in selecting a primary form include side effects, contraindications, and willingness and ability to use perfectly. (Perfect use is defined as the use of the form correctly and consistently covering every act of intercourse. Typical use reflects the practices of the average user.) All of these factors influence compliance and the chance of unwanted pregnancy.

Hormonal Combination Oral Contraceptives As A Primary Form

If the patient is currently taking or planning to take oral contraceptives, review that section in *The iPLEDGE Program Birth Control Workbook* with her. Her answers to questions on consistency and medication adherence will provide insight into potential issues with iPLEDGE Program adherence.

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Other contraception not requiring daily activity may be a better choice for a patient who is not likely to take oral contraceptives perfectly. For example, if such a patient chooses an IUD, she reduces her chances of becoming pregnant by up to approximately 90%.[1] It is critical that such a patient choose a form other than oral contraceptive agents.

Selecting An Effective Secondary Form Of Contraception

Table 2 lists the acceptable secondary forms of contraception in the iPLEDGE Program. There are 2 forms of secondary contraception: barrier and other. Barrier forms include the diaphragm and the cervical cap (both of which are always used with spermicide) and the male latex condom (which can be used with or without spermicide). The other form is the vaginal sponge, which contains spermicide.

Table 2: Secondary Forms of Contraception Listed by Typical Use Failure Rate

	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	Perfect Use	Typical Use
Barrier Forms		
Male Latex Condom[b]	2%	18%
Diaphragm[*]	6%	12%
Cervical Cap[*,d]	9%	20%
Other Forms		
Vaginal Sponge[c]	9%	12%

a Adapted from Trussell J Contraceptive failure in the United States Contraception 011;83:397–404 http: Available at: www ncbi nlm nih gov pmc articles PMC3638 09 Accessed September 9, 014

b Male Latex Condom failure rates are for use without spermicide Female condoms are not acceptable for the iPLEDGE program (See "Unacceptable Forms Of Contraception"on page 7)

c Failure rate for nulliparous women The rate is approximately double for parous women

d Adapted from Trussell J Contraceptive failure in the United States Contraception 011;83:397–404 http: Available at: www ncbi nlm nih gov pmc articles PMC3638 09 Accessed September 9, 014

Failure rates for Diaphragm and Cervical Cap are for forms including the use of spermicide

The most important issue for a secondary form is whether it will be used each time the patient has intercourse (i.e., will it be in place when the first form fails).

Help the patient select a secondary form that she and/or her partner can fully commit to using correctly each time they have intercourse. If it is apparent that more than 1 of the forms would be equally suited, select the form with the lower or lowest perfect use failure rate, as this will reduce the overall likelihood of becoming pregnant.

Unacceptable Forms Of Contraception

The following forms of contraception are not acceptable for the iPLEDGE Program:

- Progesterone-only "mini-pills,"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix[‡]

Patients currently using these forms of contraception must switch to effective forms of contraception. They must use 2 effective forms together consistently and correctly for at least 30 days and have a negative pregnancy test before beginning isotretinoin.

Emergency Contraception

- Review this section in *The iPLEDGE Program Birth Control Workbook* with the patient. (Also, see page 27 in this *iPLEDGE Program Prescriber Contraception Counseling Guide.*) She should know when to call her prescriber for possible emergency contraception. She should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms she selected.
- Emergency contraception is available over the counter.

Abstinence

If a female of reproductive potential cannot commit completely to abstinence while taking isotretinoin, she must use 2 separate, effective forms of birth control at the same time. The only exceptions are if she has had a hysterectomy, or had both of her ovaries removed (bilateral oophorectomy), or if she has been medically confirmed as post-menopausal.

[‡] A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception See page 26

Reference ID: 3956479

REFERRING TO A GYNECOLOGIST

You may want to refer your patient to a gynecologist for:

- An examination prior to starting oral contraceptive agents or a hormonal transdermal patch
- Insertion of an IUD or hormonal vaginal ring
- Fitting a diaphragm or a cervical cap
- More detailed explanation of contraception options

You should also ask for gynecologic consultation under the following circumstances:

- Your patient's history is suggestive of polycystic ovary syndrome (Stein-Leventhal syndrome). In addition to acne she may have:
  - Excessive facial hair growth (common when acne is present)
  - Obesity
  - Amenorrhea (no menstrual period) or irregular, heavy bleeding
  - Anovulation
- Your patient has irregular menses, possibly related to pregnancy; an eating disorder; or endometriosis. It is important to weigh your patient. Patients with eating disorders may:
  - Not admit to the problem
  - Be very underweight
- There are indications of sexual abuse found during the physical examination or counseling session.
- There is history or symptoms of sexually transmitted infection.

OBTAINING A SEXUAL AND BEHAVIORAL HISTORY

There are several reasons to take a sexual and behavioral history. You need to know about sexual promiscuity, risk-taking behavior, reactions to previous contraceptive medication, and current contraceptive practices to assess whether your patient is appropriate for the iPLEDGE Program. This information may help you eliminate unsuitable patients or refer those whose contraceptive needs require gynecologic referral.

General Interview Information

Preparation

Insure that your patient feels safe and comfortable.

- This is important for an effective counseling session.
- Allow time for taking the history, answering questions, and decision-making.
- A private office is more conducive to counseling than an examination room. This may permit a more open and personal exchange.
- Interruptions by other staff members and telephone calls should be discouraged.

Use open-ended questions to encourage discussion.

- Your patient may be reluctant or embarrassed to answer questions about her sexual history.
- It may help to start asking about less sensitive material.

Being objective and nonjudgmental is important in building rapport. Make sure your patient understands your questions and the information you are giving her. Listen to her use of language and tailor your language to be sure she understands.

Sexual history questions

1. Does she menstruate? Does she menstruate regularly?
   - Most females (95%) have their menstrual period every 21 to 35 days and usually in a recurrent and regular pattern. A female whose menses vary by a week or more from month to month or vary in length or quantity of flow would qualify as irregular.
2. Has she had a hysterectomy or oophorectomy?
3. Is she still menstruating?
4. Is she postmenopausal?
5. Is she sexually active?
   - If not, is there any possibility of a sexual relationship developing?
6. If she is sexually active, are her partners men, women, or both?
7. Has she ever used contraception? Does she currently use contraception?
   - If yes, what form(s) and for how long?
   - Specifically question the use of unacceptable forms such as the progesterone-only mini-pills or female condom.
8. If she uses oral contraceptives, does she take them exactly as prescribed? If so, which brands?
9. Does she use a secondary form of contraception every time she has sex? If so, which forms?
10. How many sexual partners has she had in the past 6 months? How many sexual partners does she currently have?

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11. How long has she been with her current partner(s)? Is she monogamous?
12. Has she ever had a sexually transmitted infection? Has she ever been sexually abused?
13. Has she ever been pregnant? Does she have children?
14. Has she ever had an unintended pregnancy? What was the outcome?

Behavioral history questions

1. Does she engage in risk-taking behavior, such as using drugs or alcohol?
2. How is she doing in school/at work?
3. How is her relationship with her parents? With her siblings?
4. What is her cohabitational status? Is she married? Living with a partner?
5. Is she currently using any prescription or non-prescription medications, herbal supplements, or vitamins?

Additional Guidance For Interviewing An Adolescent*

This section offers guidance on how to approach an adolescent to obtain a sexual and behavioral history, taking into consideration concerns adolescents have about independence, parental oversight, and privacy.

Discuss confidentiality first

- Inform the patient that she has a private and privileged relationship with you.
- Identify restrictions for which you may need to breach confidentiality, such as reporting physical or sexual abuse to health authorities.
- Tell her that you will not talk with her parent or parents about something she has said without discussing it with her first.

Start gently when asking about personal history

- Start with non-threatening topics and gradually move to more sensitive issues.
- Explain that you ask all of your patients about sexual activity and tell her why this information is important.
- Consider using one of the following questions to initiate the discussion about the patient's sexual history.
  - Are you dating anyone?
  - Are you intimate with anyone?
  - Are you physically close with anyone?

* Adapted from: Sexual History Taking American College of Obstetrics and Gynecology, Committee on Adolescent Health Care, ACOG Committee Opinion No 300 October 2004:p3

Identify risk behaviors

- Leave room for discussing casual sex partners (who, for example, may not be perceived as "boyfriends").
  - Did you choose to have sex?
  - Has anyone forced you to have sex?
- Establish the sex of partner or partners first. Do not assume heterosexual behavior.
- Ask about oral and anal sex, and describe what you mean by this, if necessary.
  - Anal intercourse may be used by some teenagers to preserve virginity and protect against pregnancy, so they may not be using their secondary forms.
- Ask about the number of partners, STIs (sexually transmitted infections) and pregnancy prevention methods used.
  - Specifically, ask what methods the patient is using.
  - Find out if they are using unacceptable forms of contraception such as the progesterone-only mini-pill, female condom, or withdrawal.

Keep the lines of communication open

- Encourage adolescents to discuss these issues with their parents. You can assist the adolescent in telling her parents about her sexual activity and her need to use 2 forms of contraception for the iPLEDGE Program.
- Congratulate the patient for showing ability to think about her sexual health and be responsible.

CONTRACEPTION REFERENCE MATERIAL

The following sections contain some pertinent details, advantages, and disadvantages of the **primary** and **secondary** forms of effective contraception. This is not complete product information. Please refer to individual product labeling for contraindications, warnings and precautions, instructions for use, adverse events, and other product-specific information.

The percentages that follow for perfect use and typical use of a contraceptive are percentages of females having an unintended pregnancy during the first year of use, expressed as "1 female in X years."[2] Perfect use is defined as the use of the form correctly and consistently covering every act of intercourse. Typical use reflects the practices of the average user.

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PRIMARY FORMS OF CONTRACEPTION

The effective primary forms of birth control fall into 3 categories:

- Combination Hormonal Contraceptives
- Single Hormonal Contraceptives
- Non-Hormonal Contraceptives

None of the primary forms protect against STIs (sexually transmitted infections) or HIV (AIDS).

Combination Hormonal Contraceptives

Combination hormonal contraceptives include combination oral contraceptives, the transdermal patch, the vaginal ring, and hormonal implants. They use estrogen and a progestin in combination to suppress ovulation. In general, these forms have similar contraindications and adverse event profiles.

Hormonal Combination Oral Contraceptives[3]

With perfect use, the failure rate for combination oral contraceptives is equal to that of the best currently available contraceptive measure. **With typical use, oral contraceptives have the highest failure rate of the effective primary forms (Table 1).** Do not prescribe combination oral contraceptives for patients whom you do not think will take them exactly as prescribed. Other primary forms that do not require daily action by the patients, such as an IUD, may be a better choice for reducing the likelihood of pregnancy.

Note: Progesterone-only contraceptives (mini-pill) are not acceptable for the iPLEDGE Program because they are not an effective form of birth control. If your patient is using them, she will have to choose another effective primary form of birth control.

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)
Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Mechanism of action

Suppression of ovulation

Contraindications

- Thrombophlebitis disorders, history of deep vein thrombosis (DVT), or thromboembolic disorder
- Cerebral vascular or coronary artery disease
- Migraine with focal aura
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Acute or chronic hepatocellular disease with abnormal liver function
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy
- Hypersensitivity to product
- Smoking and over the age of 35

Other warnings

- Female patients with significant hypertension should not be started on oral contraceptives.
- Female patients who have had major surgery with immobilization or any leg surgery should not be started on oral contraception.
- Cigarette smoking increases the risk of serious cardiovascular adverse events with oral contraceptives. Female patients who use oral contraceptives should be strongly advised not to smoke. This risk is increased for female patients over 35 and those who smoke more than 15 cigarettes a day.
- Increased risk of venous thromboembolism and stroke.

Instructions for use

Once daily for hormone pills for a specified time period, often followed by placebos for a specified number of days. The patient should take oral contraceptives exactly as prescribed.
Missed pill(s):

- Any missed pills: discontinue intercourse for the remainder of the cycle
- Missed more than 2 pills: instruct the patient to call as soon as she realizes that she has missed 2 or more pills; she should be evaluated for possible emergency contraception, depending on her sexual activity. The patient should be counseled not to have intercourse for the rest of the cycle.

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Advantages

- May decrease the risk of the following:
  - endometrial and ovarian cancer
  - functional ovarian cysts
  - pelvic inflammatory disease
  - benign breast disease
  - ectopic pregnancy
- May decrease the incidence of dysmenorrhea and acne

Disadvantages

- Combination oral contraceptives do not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Common adverse events include breakthrough bleeding, nausea and vomiting, and headaches
- Associated with an increased risk of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease
- Less effective with medications affecting hepatic metabolism such as anticonvulsants; may be less effective with the antibiotics rifampin and griseofulvin,* possible interaction with St. John's Wort
- Isotretinoin may make hormonal forms less effective
- If pills are skipped or missed, the risk of pregnancy is very high

Hormonal Transdermal Patch[4]

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)

Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Contraindications

See "Contraindications," page 13.

Instructions for use

One patch is used per week for 3 consecutive weeks, on the same day of the week. The fourth week is patch-free. Menses occurs at this time.

If the female patient is starting the patch for the first time, she should wait until the day she begins her menstrual period.

*Adapted from ACOG Practice Bulletin, Number 18, July 2000

Slipped or missed patches:

- If the patch falls off or is partially detached for less than 24 hours, the patient can reapply in the same place. Otherwise, replace with a new patch immediately. Change patches on the original schedule.
- If the patch is detached for more than 1 day or the patient is not sure how long the patch was detached, she should start a new cycle with a new change day by applying a new patch. It will not be effective for contraception for the first week.
- The patient should be instructed not to have intercourse during this first week.

Advantages

- It is not necessary to remember to take a daily pill
- Many female patients have more regular, lighter, and shorter periods
- Fertility returns quickly when the patch is stopped

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Less effective in female patients over 198 pounds
- Not effective if it becomes loose or falls off for more than 24 hours or if the same patch is left on the skin for more than 1 week
- Has the same labeling for contraindications, warnings, and precautions as oral contraceptives
- Common side effects include breakthrough bleeding, nausea, headaches and breast tenderness.
- Isotretinoin, antibiotics, St. John's Wort, and certain anticonvulsants may make hormonal forms less effective
- Possible increased risk of blood clots

Hormonal Vaginal Ring[5,6]

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)
Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Contraindications

See "Contraindications," page 13.

Reference ID: 3956479

Instructions for use

Patient inserts ring in the vagina, where it should remain for 3 weeks. She removes ring for 1 week to bring on menses. A new ring is used each month for continuous contraception.

Advantages

- It is not necessary to remember to take a daily pill
- It does not need to be fitted by a clinician
- Many female patients have more regular, lighter, and shorter periods
- Fertility returns quickly when the ring is stopped

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- The ring cannot be used with a diaphragm or cervical cap
- Some female patients may have trouble inserting the ring
- It has the same labeling for contraindications, warnings, and precautions as oral contraceptives
- Efficacy of the ring is lessened if:
  - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
  - It slips out of the vagina and is not replaced in 3 hours
  - It does not stay in the vagina for 3 weeks
  - It is left in the vagina for more than 3 weeks
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective

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Single Hormone Contraceptives (Progestin-only)

Single hormone forms contain a progestin that can suppress ovulation, thicken cervical mucus, and produce endometrial atrophy. Accepted forms include single hormone injection, the hormonal IUD, and implantable hormones. **Note: oral contraceptives containing no estrogen (progestin-only "mini-pills" see page 7) are not an acceptable form of contraception during isotretinoin therapy.**

Single Hormone Injections[3]

Rate of unintended pregnancies

Perfect Use: 0.2% (1 female in approximately 500 will become pregnant)
Typical Use: 6.00% (1 female in approximately 17 will become pregnant)

Contraindications

Pregnancy, unexplained abnormal vaginal bleeding, breast cancer or significant liver problems

Instructions for use

Injection every 12 weeks (150 mg/1 cc IM)

Advantages

- It works for 12 weeks at a time
- There is no daily pill to take
- It is good for female patients who cannot take estrogen

Disadvantages

Black Box Warning: Prolonged use of this [drug] may result in significant loss of bone density, and loss is greater the longer the drug is administered. Bone density loss may not be completely reversible after discontinuation of the drug. A female should only use this [drug] as a long-term birth control form (for example, longer than 2 years) if other birth control forms are inadequate for her.

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It can cause irregular bleeding
- It requires healthcare professional visit for injection every 12 weeks
- If patient is planning to get pregnant *after* she finishes isotretinoin treatment, it may take up to 18 months for return of ovulation.
- Isotretinoin may make single hormonal forms less effective

Reference ID: 3956479

Hormonal Intrauterine Device (IUD)[3,7]

The hormonal IUD is indicated for contraception in female patients who have had at least 1 child, are in a monogamous relationship, and are at low risk for STIs (sexually transmitted infections).

Rate of unintended pregnancies

Perfect Use: 0.2% (1 female in 500 will become pregnant)
Typical Use: 0.2% (1 female in 500 will become pregnant)

Contraindications

- Pregnancy or suspicion of pregnancy
- Congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity
- Acute pelvic inflammatory disease (PID) or history of PID without subsequent intrauterine pregnancy
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical neoplasia or unresolved, abnormal Pap smear
- Carcinoma of the breast
- Genital bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis, lower genital tract infections
- Acute liver disease or liver tumor (benign or malignant)
- Female patient or her partner has multiple sexual partners
- Conditions associated with increased susceptibility to infections with microorganisms
- Genital actinomycosis
- Previously inserted IUD that has not been removed
- History of ectopic pregnancy or condition that would predispose to ectopic pregnancy

Instructions for use

The IUD is inserted by a healthcare professional. The patient should check for IUD strings often in the first few months after insertion and after each period. If the patient cannot find the strings, the strings feel shorter or longer, she can feel the IUD itself, there are any signs of symptoms of PID, or she misses a period, instruct her to call her prescriber.

Advantages

- It can be used for long-term contraception (5 years) and is relatively quickly reversible (i.e., return to fertility).

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It requires insertion and removal by a healthcare professional
- Common adverse events include menstrual changes, lower abdominal pain and cramping, acne or other skin problems, back pain, breast tenderness, headache, mood changes, nausea
- Enlarged ovarian follicles have been diagnosed in about 12% of hormonal IUD users; most disappear spontaneously during 2 to 3 months of observation
- All types of IUDs may increase the risk of pelvic inflammatory disease (PID); side effects of all types of IUDs may include cramps and heavier and longer periods in the first few months after it is placed
- IUD may be expelled, often during menses
- Isotretinoin, antibiotics, St. John's Wort, and certain anticonvulsants may make hormonal forms less effective
- IUDs may cause menstrual changes or amenorrhea
- If a pregnancy occurs, it is more likely to result in an ectopic pregnancy

Implantable Hormones[3]

Description

Implantable hormones (etonogestrel implant) are a long acting (up to 3 years), reversible method of progestin only contraception. This form of contraception involves a sterile rod(s), the size of a matchstick, for subdermal insertion under the skin on the inner side of the upper arm during a minor in-office surgical procedure.

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Rate of Unintended pregnancies

Perfect Use: 0.05% (1 female in 2000 will become pregnant)

Typical Use: 0.05% (1 female in 2000 will become pregnant)

Contraindications

- Known or suspected pregnancy
- Current or past history of thrombosis or thrombotic disorders
- Hepatic tumors (benign or malignant), active liver disease
- Undiagnosed abnormal genital bleeding
- Known or suspected carcinoma of the breast or personal history of breast cancer
- Hypersensitivity to any of the components of the implant

Advantages

- Effective birth control for up to 3 years
- It is not necessary to remember to take a daily pill
- Fertility may return quickly when Implant is removed
- Can be used in patients who cannot take estrogen

Disadvantages

- Implant does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- May cause irregular and unpredictable bleeding or amenorrhea.
- Other side effects can include headache, acne, dysmenorrhea and emotional lability
- Associated with an increased risk of myocardial infarction, thromboembolism, stroke, hepatic neoplasia and gall bladder disease
- Complications of insertion can include: swelling, redness, pain, bruising, scarring, infection, paresthesias, bleeding, and hematoma
- Complications of removal include: a broken rod, scar tissue making removal more difficult
- Rarely, it can be difficult or impossible to remove which may result in a surgical procedure

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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- If pregnancy occurs, there is a higher chance of an ectopic pregnancy
- Ovarian cysts that usually disappear spontaneously
- Studies were not done in women who weighed more than 130% of their ideal body weight or patients who are chronically taking medication that induce liver enzymes, and it is possible that the implant may be less effective in women who are overweight
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective

If you use an implant, always verify its presence in the patient's arm immediately after insertion by palpation. Until you confirm proper insertion, your patient must use a non-hormonal contraceptive method and is not eligible to start isotretinoin.

Non-hormonal Contraceptives[3,8]

Accepted non-hormonal forms of contraception include the Cu T 380A IUD, tubal sterilization, and partner's vasectomy. These non-hormonal forms do not protect against STIs (sexually transmitted infections) or HIV.

Cu T 380A IUD

Perfect Use: 0.6% (1 female in approximately 166 will become pregnant)
Typical Use: 0.8% (1 female in 125 will become pregnant)

Description

Made of polyethylene covered with copper

Mechanism of action

Prevents fertilization by altering tubal and uterine transport of sperm

Contraindications

- Pregnancy or suspicion of pregnancy
- Abnormalities of the uterus resulting in distortion of the uterine cavity
- Acute pelvic inflammatory disease (PID) or a history of PID
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical malignancy, including unresolved, abnormal Pap smear
- Genital bleeding of unknown etiology

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- Untreated acute cervicitis or vaginitis, including bacterial vaginosis, until infection is controlled
- Diagnosed Wilson's disease
- Known allergy to copper
- Female patient or her partner has multiple sexual partners
- Genital actinomycosis
- A previously inserted IUD that has not been removed

Instructions for use

Patient should check for IUD strings often in first few months after insertion and after each period. If patient cannot find the strings, the strings feel shorter or longer, she can feel the IUD itself, there are any signs of symptoms of PID, or she misses a period, she should call her prescriber.

Advantages

- Female patients who cannot take hormones can use it
- It can be used for long-term contraception (10 years) and is relatively quickly reversible (i.e., return to fertility)

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It requires insertion and removal by a healthcare professional
- It should be used in female patients who are not at risk for STIs (sexually transmitted infections)
- All types of IUDs may increase the risk of pelvic inflammatory disease (PID)
- Side effects of all types of IUDs may include cramps, and heavy, longer periods
- The IUD may be expelled, often during menses

Sterilization[3]

Female sterilization may be accomplished using a variety of techniques. They are all considered to be very effective, virtually permanent methods of pregnancy prevention and, with the exception of hysteroscopic tubal sterilization, are immediately effective. For purposes of the iPLEDGE Program, a patient should not be permitted to consider her hysteroscopic tubal sterilization as an accepted method of contraception unless she has had a confirmatory hysterosalpingogram (HSG) or other confirmation.

A partner's vasectomy involves the mechanical blocking of the vasa deferentia in males. This is an effective primary form of contraception which prevents fertilization by keeping sperm from entering the seminal fluid. Males should have semen analysis after 15 to 20 ejaculations to be sure semen is free from sperm. If the patient has more than 1 partner, each partner must be sterilized for male sterilization to be effective as the patient's only primary form. If the patient uses male sterilization as a primary form, she should be encouraged to choose another primary form as a second form.

Rates of unintended pregnancies

Tubal sterilization

Perfect Use: 0.5% (1 female in 200 will become pregnant)
Typical Use: 0.5% (1 female in 200 will become pregnant)

Partner's vasectomy

Perfect Use: 0.1% (1 female in 1,000 will become pregnant)
Typical Use: 0.15% (1 female in approximately 666 will become pregnant)

Advantages (for tubal sterilization)

- Very effective, virtually permanent means of contraception

Disadvantages (for tubal sterilization)

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Difficult to reverse
- Requires surgery
- If a pregnancy does occur, there is an increased risk of an ectopic pregnancy

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Advantages (for partner's vasectomy)

- Very effective, virtually permanent means of contraception

Disadvantages (for partner's vasectomy)

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Low success rate in reversing
- Requires surgery
- Not effective right away

Please see accompanying complete product information, including boxed
CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and **ADVERSE REACTIONS.**

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SECONDARY FORMS OF CONTRACEPTION

Most of the secondary forms are barrier contraceptives that prevent sperm from entering the vagina (condom) or cervix (diaphragm and cervical cap). Barrier forms include the diaphragm and the cervical cap, both of which must be used with spermicide. The male latex condom can be used with or without spermicide. The vaginal sponge is a delivery system for spermicide and has spermicide embedded in it. Female condoms are not acceptable for the iPLEDGE Program.

Diaphragms and cervical caps are barrier contraceptives that are considered moderately effective when used in combination with a spermicide. The male latex condom is a barrier contraceptive that is considered moderately effective when used with or without spermicide. The vaginal sponge is also considered moderately effective. The most important issue is whether the secondary form will be used each time the patient has intercourse. If the patient selects a secondary form as the second form of contraception, she must understand how it is used and be fully committed to using it each time she has intercourse.

Female patients under 30 and female patients who have intercourse 3 or more times per week may have a higher failure rate with vaginal secondary forms.

Note: The female condom, a thin, flexible plastic tube that covers the cervical os, is not an acceptable secondary form for the iPLEDGE Program.

Male Latex Condom Used With or Without Spermicide[3]

If the patient does not feel she can convince her partner(s) to use a latex condom (with or without spermicide) each time they have intercourse, she would need to select another secondary form where she has the control or select a second primary form.

Rate of unintended pregnancies

Perfect Use: 2% when used without spermicide (1 female in 50 will become pregnant)
Typical Use: 18% when used without spermicide (1 female in 6 will become pregnant)

Male condom (Latex) may be used with or without spermicide

Instructions for use

Unrolled onto erect penis before there is any contact with female genitals; use only water-based lubricants with latex condoms

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Advantages

- Protects against STIs (sexually transmitted infections) and HIV (AIDS)
- Easy to buy, no doctor appointment needed, no pelvic exam needed
- Easy to tell when it breaks or slips, important for seeking emergency contraception
- May lower risk of cervical dysplasia and cancer[12]

Reference ID: 3956479

Disadvantages

- Condoms can break or slip during sex
- May decrease sensitivity and spontaneity, may have trouble maintaining erection
- Must remember to use every time

Diaphragm Used With Spermicide[3,9]

Rate of unintended pregnancies

Perfect Use: 6% when used with spermicide (1 female in approximately 17 will become pregnant)
Typical Use: 12% when used with spermicide (1 female in approximately 8 will become pregnant)

Description

Dome-shaped rubber cap with a flexible rim available in many sizes (50-95 mm diameter) and different styles

Warnings

- There is an association between Toxic Shock Syndrome (TSS) and diaphragm use.
- A diaphragm must be removed after 6 to 8 hours to decrease the risk of TSS.
- There may be increased risk of urinary tract infections, candidiasis, or bacterial vaginosis.
- A diaphragm may cause allergic reactions in females sensitive to latex or rubber.

Advantages

- Female patients can easily carry a diaphragm with them and have control of its use
- Immediately effective
- No hormones
- No interruption of sex play; can be inserted any time before intercourse and must stay in place for at least 6 to 8 hours after intercourse; a diaphragm should not be worn for more than 24 hours
- May lower risk of cervical dysplasia and cancer
- Can be used during a menstrual period

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Requires a prescription, pelvic examination, and periodic refitting; lasts about 1 to 2 years

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- Some female patients find it hard to insert
- Spermicide must be inserted in the vagina if there is repeated intercourse
- Can get pushed out of place during sex
- Must be checked for holes after sex and cleaned after use

Cervical Cap Used With Spermicide[3,10]

Rate of unintended pregnancies in nulliparous females

Perfect Use: 9% when used with spermicide (1 female in approximately 11 will become pregnant)

Typical Use: 20% when used with spermicide (1 female in 5 will become pregnant)

The failure rate is double in parous females.

Description

Deep rubber cap with firm rim and a groove inside the rim that fits snugly around the cervix

Advantages

- Same as diaphragm
- No need to add more spermicide if female patient has repeated intercourse
- Continuous protection for 48 hours

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Some female patients find it harder to insert than a diaphragm
- It cannot be used during a menstrual period
- Patient needs a prescription and a pelvic examination to fit a cervical cap; a cap lasts about 1 year.
- Must be checked for holes and tears after sex and cleaned after use
- Less effective with multiparous females

Vaginal Sponge (Contains Spermicide)[3,11]

Rate of unintended pregnancies in nulliparous females:

Perfect Use: 9% (product contains spermicide) (1 female in approximately 11 will become pregnant)

Typical Use: 12% (product contains spermicide) (1 female in approximately 8 will become pregnant)

The failure rate is double in parous females.

Description

Soft, disposable, non-abrasive polyurethane foam that is a delivery system for 1 gram of the spermicide, Nonoxynol-9

Advantages

- Female patients can easily carry a vaginal sponge with them and have control of its use
- Immediately effective
- No hormones
- No interruption of sex play; can be inserted any time before intercourse and is effective for up to 24 hours
- No need to put in more spermicide with repeated intercourse
- No special fitting, available over the counter
- Not associated with TSS

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Less effective with multiparous females

EMERGENCY CONTRACEPTION[3]

Emergency contraception is indicated after sex without adequate protection:

- No contraception is used
- A secondary form slips or breaks
- Missed pill or injection
- Rape

Emergency contraception is provided as either emergency hormonal contraception or insertion of a Cu T 380A IUD.

Hormonal Emergency Contraception Pills (ECPs)

Emergency contraception is available without a prescription regardless of age. Patients must understand that the sooner ECPs are started, the more likely they are to be effective. Common side effects include nausea and vomiting. Consider prescribing medication to reduce these side effects.

Always consult complete Prescribing Information for any medications prescribed or currently being taken by your patient.

Reference ID: 3956479

Insertion of Cu T 380A IUD

The IUD is inserted within 5 days of unprotected sexual intercourse. IUD insertion for emergency contraception is not recommended for female patients who have not had a child or are at risk for sexually transmitted infections. These include female patients with more than 1 sex partner or whose partners have more than 1 partner, female patients with new partners, and female patients who have been raped.

The names and phone numbers of emergency contraception prescribers in your area can be obtained by calling toll free: 1-888-NOT-2-LATE (1-888-668-2528).

REPORTING A PREGNANCY

The iPLEDGE Program Pregnancy Registry

The iPLEDGE Program Pregnancy Registry collects data on pregnancies that occur in female patients who become pregnant while taking isotretinoin or within 30 days of their last dose. Data from the registry are reported to the FDA and are used to assess the effectiveness of the iPLEDGE Program. The data are also used to evaluate further ways to reduce fetal exposure. Information gathered in the iPLEDGE Program Pregnancy Registry will be used for statistical purposes only and will be held in the strictest confidence.

The prescriber must report to the iPLEDGE Program Pregnancy Registry any pregnancy case that he/she becomes aware of while the female patient is on isotretinoin or 1 month after the last dose. Report a pregnancy by calling **1-866-495-0654**. Select the option to **"Report a Pregnancy."** All pregnancies should also be reported to the FDA via the MedWatch number: 1-800-FDA-1088.

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FemCap® is a registered trademark of FemCap Inc

Mirena® is a registered trademark of the Berlex Corporation

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OrthoEvra® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc

Today® Sponge is a registered trademark of Allendale Pharmaceutical, Inc

NOTES:

For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call **1-866-495-0654**.

Confidential birth control information can be obtained via the iPLEDGE automated phone line 24 hours a day, 7 days a week at **1-866-495-0654**. The subjects include:

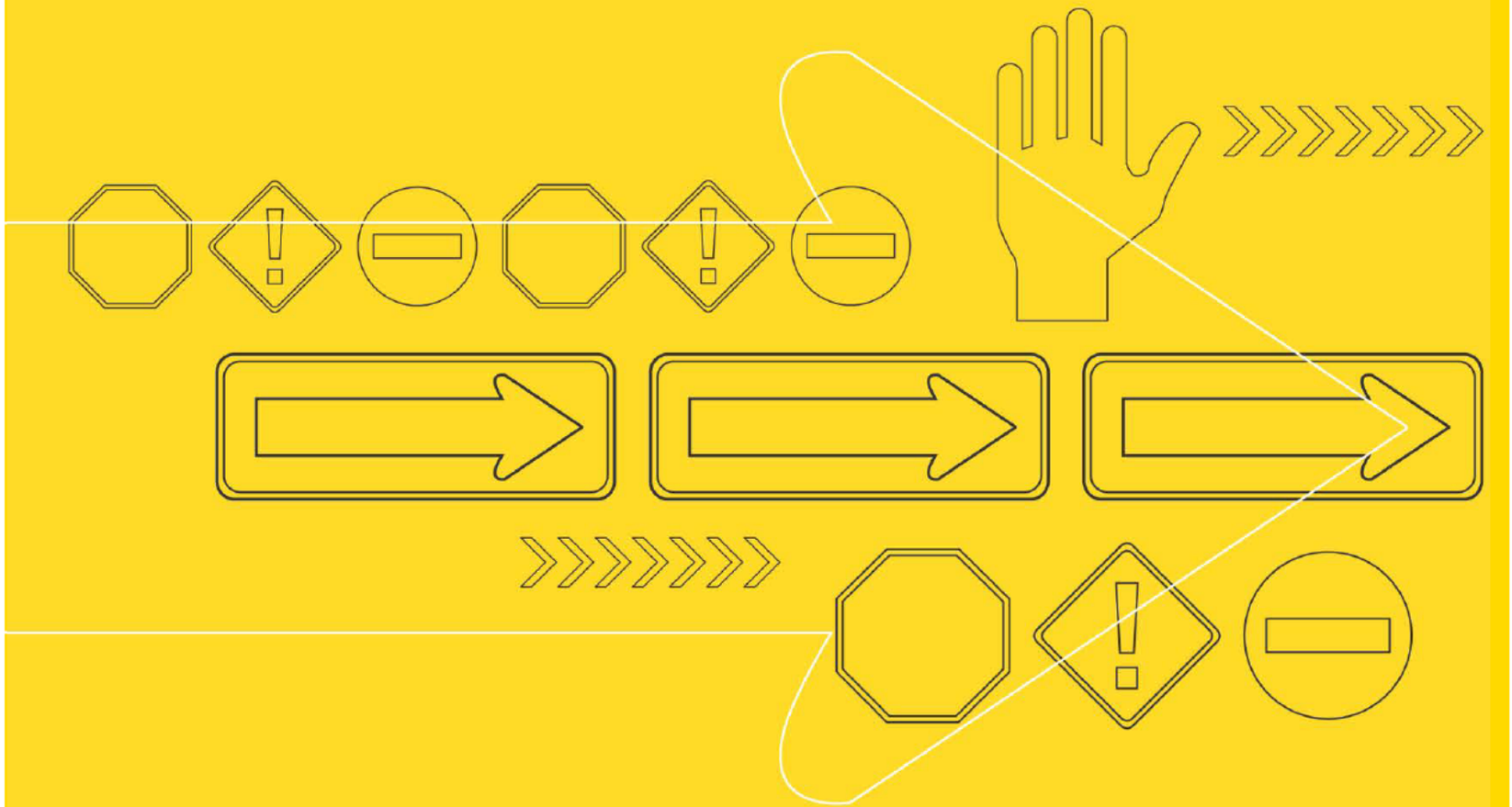
1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-O654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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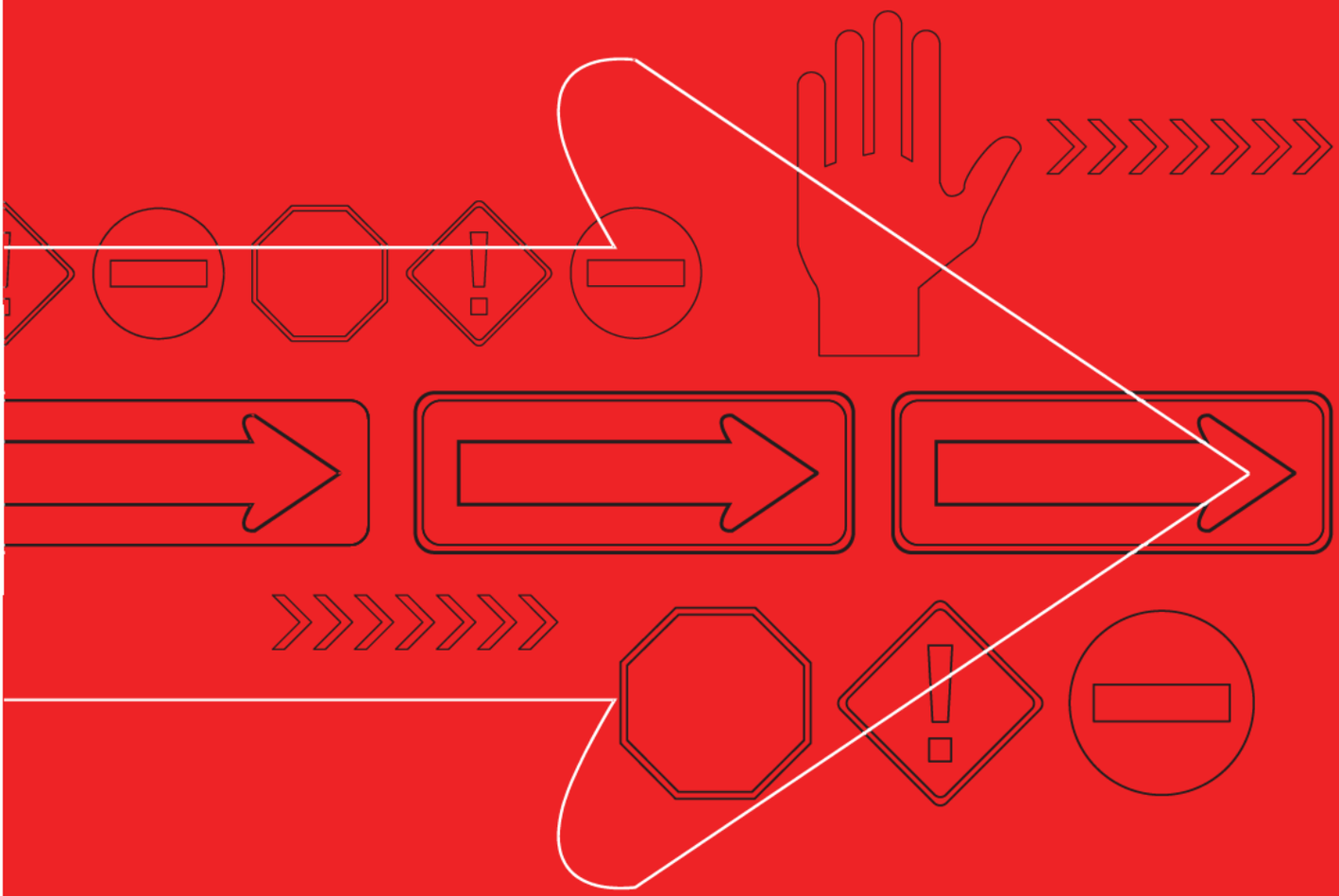
Recognizing Psychiatric Disorders In Adolescents And Young Adults



A guide to recognizing psychiatric disorders in adolescents and young adults for prescribers of isotretinoin

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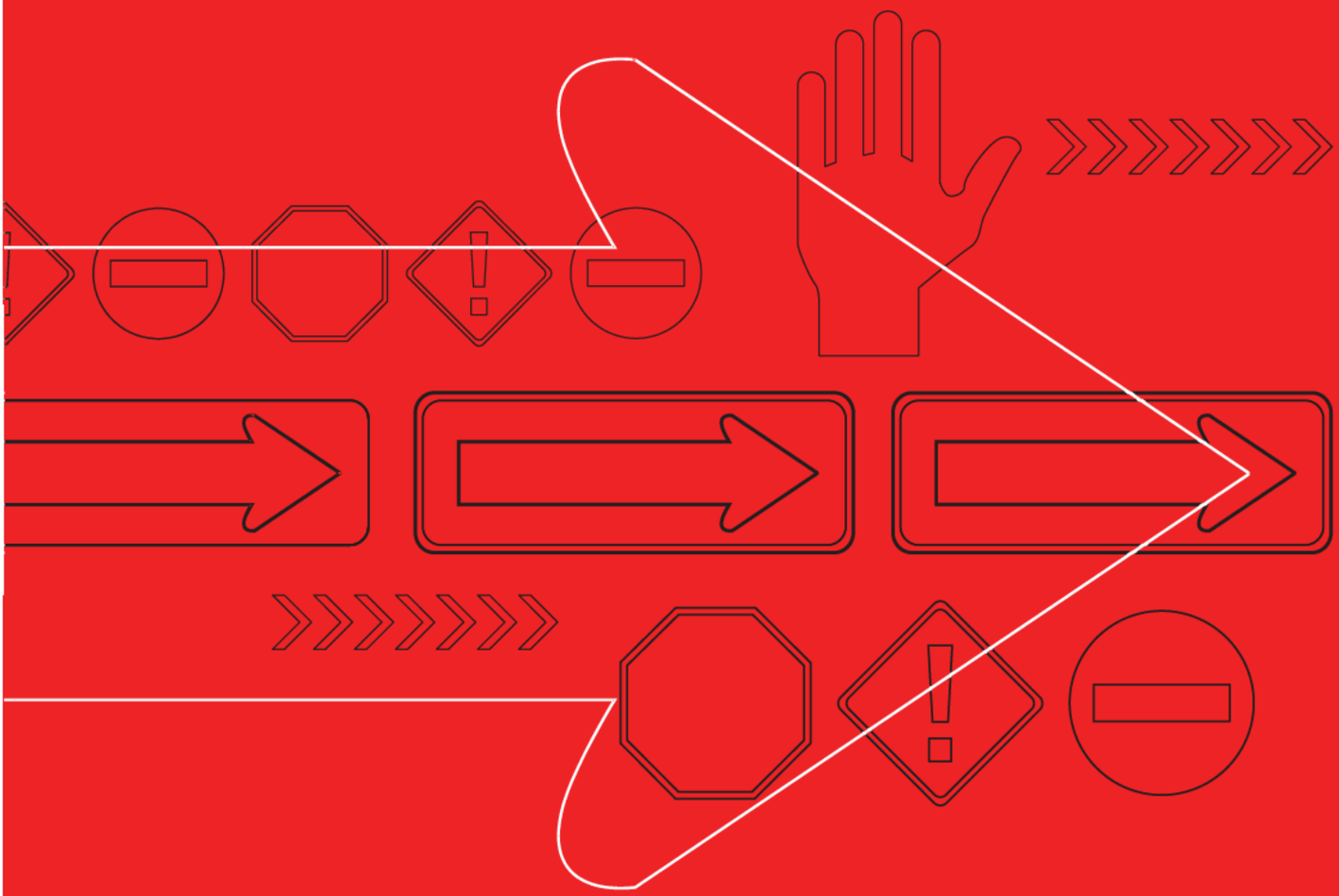
Educational Video



An educational video to share with patients

Reference ID: 3956479
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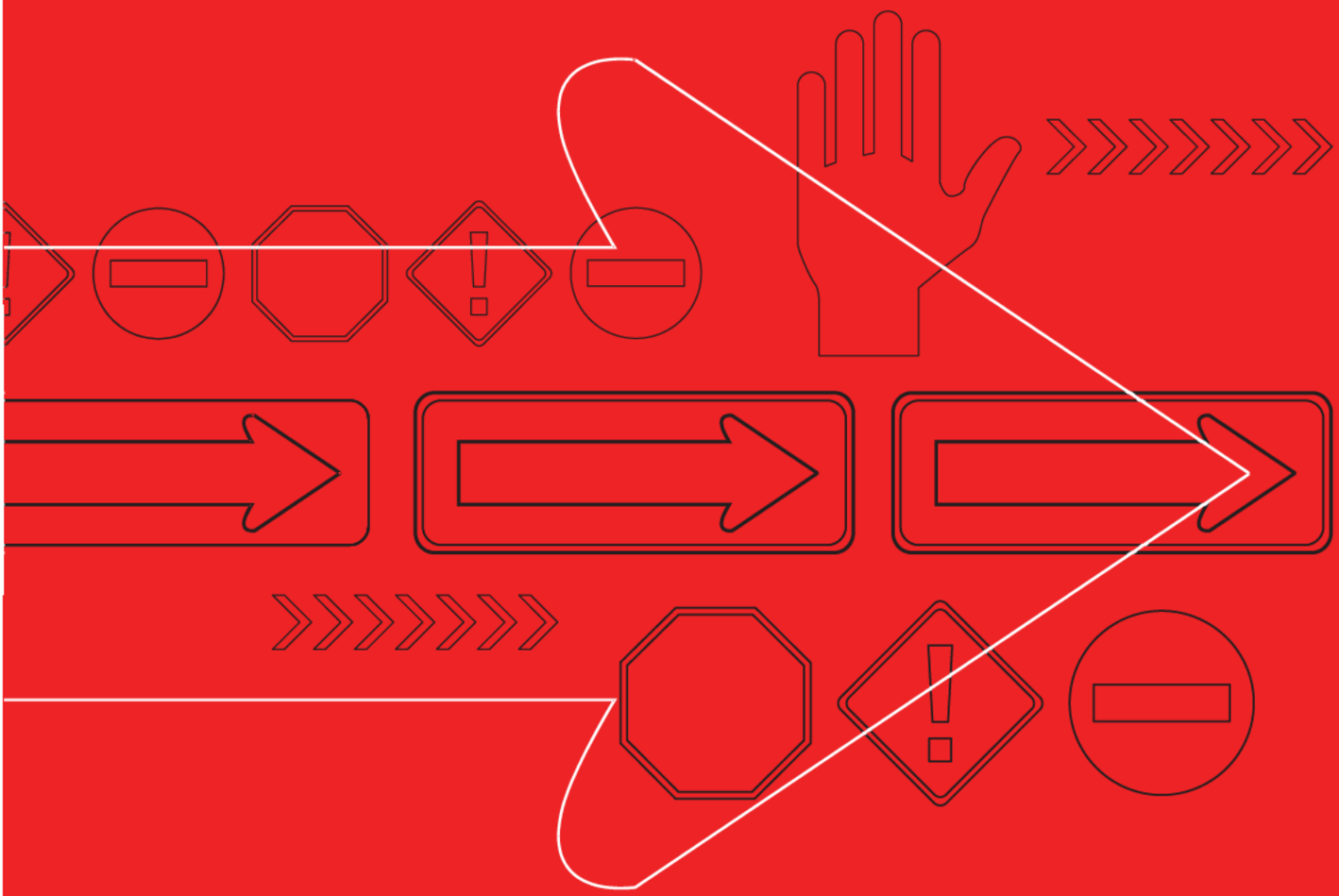
Educational material contains the following 2 videos

- *Be Prepared, Be Protected,* a video about pregnancy prevention
- *Be Aware: The Risk of Pregnancy While on Isotretinoin,* a video about birth defects

Reference ID: 3956479

Prescriber Flowchart



A flowchart to assist the prescriber with the iPLEDGE Program requirements

Reference ID: 3956479

REGISTERED AND ACTIVATED PRESCRIBER

iPLEDGE™
Committed to Pregnancy Prevention

BEFORE TREATMENT

Females of reproductive potential (FRP)

- **Educate** the patient about isotretinoin and contraception requirements of the iPLEDGE Program
- **Screen** by obtaining a negative pregnancy test
- **Obtain** a signed Patient Information/Informed Consent (for all patients) form for treatment
- **Obtain** a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- **Register** patient in the program and provide patient ID card
- **Counsel** patient, or refer to an expert, that she must use 2 effective forms of contraception simultaneously for at least 1 month before starting therapy
- **Order** pregnancy tests using a CLIA-certified lab during the first 5 days of the menstrual cycle (patients with amenorrhea/irregular cycle, please refer to the PI)
- **Access*** the system to confirm patient counseling of program and contraception requirements, and to enter pregnancy test result and the patient's forms of contraception
- **Provide** a prescription for a maximum 30-day supply

Male patients/Females of non-reproductive potential (FNRP)

- **Educate** patient about isotretinoin
- **Obtain** a signed Patient Information/Informed Consent (for all patients) form for treatment
- **Register** patient in the program and provide patient ID card
- **Access*** the system to confirm patient counseling of program requirements
- **Provide** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

Females of reproductive potential (FRP)

- **Counsel** patient on program and contraception requirements
- **Order** a pregnancy test using a CLIA-certified lab
- **Access*** the system to confirm patient counseling of program and contraception requirements and to enter pregnancy test result and the patient's forms of contraception
- **Provide** a prescription for a maximum 30-day supply

Male patients/Females of non-reproductive potential (FNRP)

- **Counsel** patient on program requirements
- **Access*** the system to confirm patient counseling of program requirements
- **Provide** a prescription for a maximum 30-day supply

AFTER TREATMENT

Females of reproductive potential (FRP)

- **Counsel** the patient to use 2 forms of contraception every time she has intercourse for at least 1 month after last dose
- **Counsel** the patient not to donate blood for 1 month after last dose
- **Order** a pregnancy test using a CLIA-certified lab immediately after the last dose
- **Order** a pregnancy test 1 month after the last dose
- **Access*** the system to enter pregnancy test results after every pregnancy test

Male patients/Females of non-reproductive potential (FNRP)

- **Counsel** patient not to donate blood for 1 month after last dose

*You can access the system via the web site, **www.ipledgeprogram.com**, or the telephone, **1-866-495-0654**.

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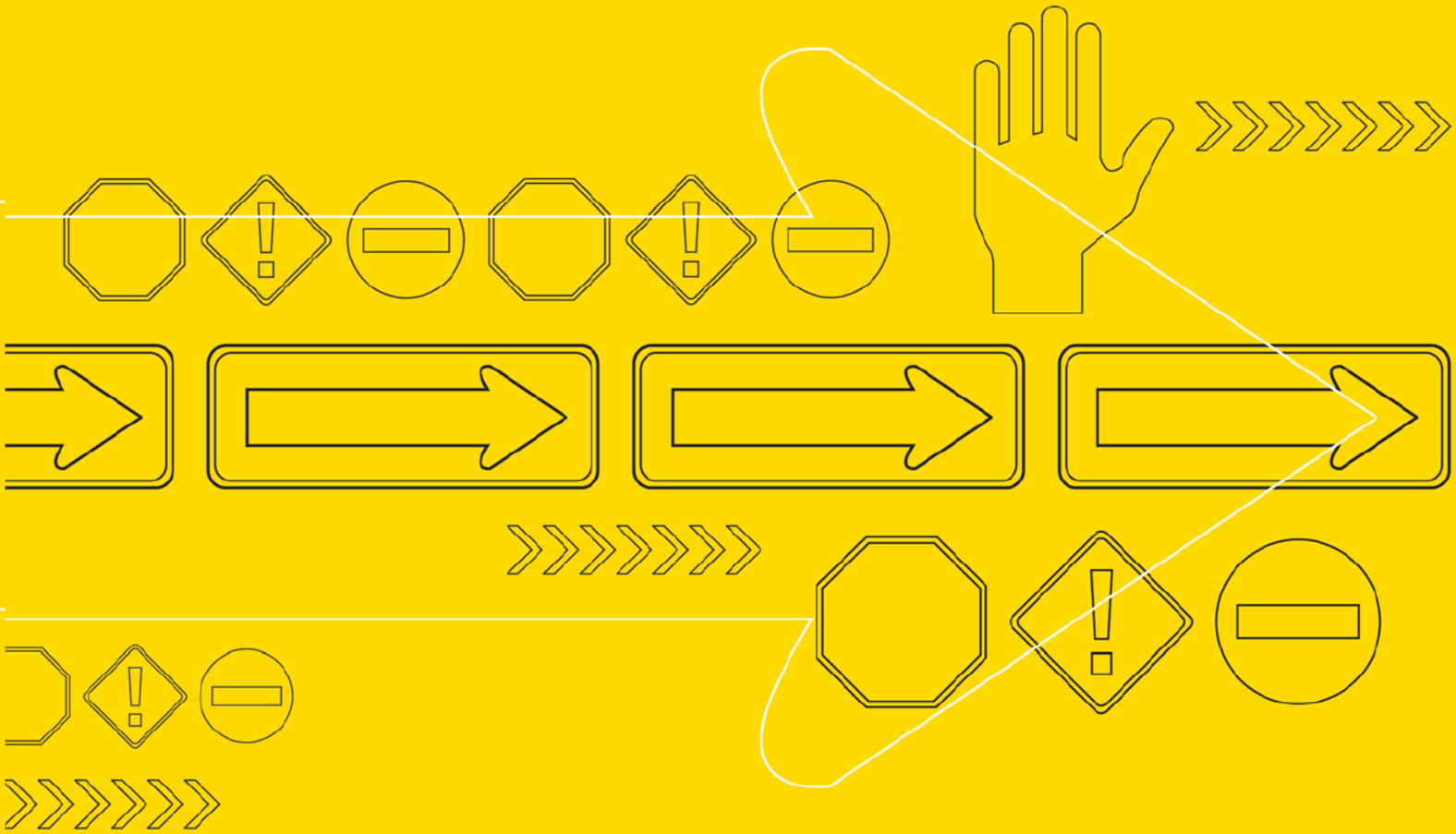

www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Recognizing Psychiatric Disorders In Adolescents And Young Adults

A Guide For Prescribers Of Isotretinoin

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

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Recognizing Psychiatric Disorders In Adolescents And Young Adults: A Guide For Prescribers Of Isotretinoin

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CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see **PRECAUTIONS**).

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Warnings

Psychiatric Disorders: Isotretinoin may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. No mechanism of action has been established for these events (see ADVERSE REACTIONS: Psychiatric). Prescribers should read the brochure, *Recognizing Psychiatric Disorders In Adolescents And Young Adults: A Guide For Prescribers Of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of isotretinoin therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary. Signs and symptoms of depression, as described in the brochure *Recognizing Psychiatric Disorders In Adolescents And Young Adults*, include sad mood, hopelessness, feelings of guilt, worthlessness or helplessness, loss of pleasure or interest in activities, fatigue, difficulty concentrating, change in sleep pattern, change in weight or appetite, suicidal thoughts or attempts, restlessness, irritability, acting on dangerous impulses, and persistent physical symptoms unresponsive to treatment. Patients should stop isotretinoin and the patient or a family member should promptly contact their prescriber if the patient develops depression, mood disturbance, psychosis, or aggression, without waiting until the next visit. Discontinuation of isotretinoin therapy may be insufficient; further evaluation may be necessary. While such monitoring may be helpful, it may not detect all patients at risk. Patients may report mental health problems or family history of psychiatric disorders. These reports should be discussed with the patient and/or the patient's family. A referral to a mental health professional may be necessary. The physician should consider whether isotretinoin therapy is appropriate in this setting; for some patients the risks may outweigh the benefits of isotretinoin therapy.

Pseudotumor Cerebri: Isotretinoin use has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided. Early signs and symptoms of pseudotumor cerebri include papilledema, headache, nausea and vomiting, and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, they should be told to discontinue isotretinoin immediately and be referred to a neurologist for further diagnosis and care (see ADVERSE REACTIONS: Neurological).

Adverse Reactions

Neurological: pseudotumor cerebri (see WARNINGS: Pseudotumor Cerebri), dizziness, drowsiness, headache, insomnia, lethargy, malaise, nervousness, paresthesia, seizure, stroke, syncope, weakness

Psychiatric: suicidal ideation, suicide attempts, suicide, depression, psychosis, aggression, violent behaviors (see WARNINGS: Psychiatric Disorders), emotional instability

Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.

Reporting adverse events

Specific information about adverse events that may occur during isotretinoin therapy may be reported to the individual makers of isotretinoin and/or to the Food and Drug Administration MedWatch Program at 1-800-FDA-1088 or via www.fda.gov/medwatch/report.htm.

The contact information for specific brands of isotretinoin can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Isotretinoin

Isotretinoin is a retinoid related to vitamin A. Patients should be advised against taking vitamin supplements containing vitamin A to avoid additive toxic effects.

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Introduction

Mental health problems are underdiagnosed and undertreated.[1] Dermatologists and other isotretinoin prescribers often see patients who are otherwise healthy, and they may be among the only professionals who have opportunities to evaluate patients' mental health. Healthcare providers who recognize the signs and symptoms of psychiatric illness and respond appropriately can improve, and perhaps even save, their patients' lives.

Isotretinoin may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Although causality has not been established for these reports, awareness of signs and symptoms may save your patient's life. This brochure provides an overview of depression. The goal of this brochure is to help you identify when a psychiatric consult is advisable.

You and your staff may feel uncomfortable evaluating your patients' mental health status. It is often difficult to distinguish clinical depression from other responses. It may also be difficult to decide whether erratic behavior may warrant psychiatric evaluation, especially if that behavior seems to be age-appropriate in a teenager. However, as with any specialize problem, you may identify patients who seem to need more than dermatologic care, and you may need to refer them to a specialist. Knowing when to make a referral for a patient who may be at psychiatric risk can make a major difference in the patient's life. In extreme cases, it can mean the difference between life and death.

Depression

Depression and suicidal tendencies are two important psychiatric conditions that may be observed in dermatology and family practice settings. This brochure provides an overview of depression because depression is the most commonly reported psychiatric adverse event in patients taking isotretinoin and is also a well established risk factor for suicidal behavior.

Depression is characterized by symptoms that include intense, persistent sadness; anxiety; loss of pleasure from usual activities; and loss of energy.[2] These feelings can be normal responses to a negative life event, but clinical depression is either not triggered by such an event or is disproportionate to the trigger.[3]

Depression can be episodic. According to the National Comorbidity Survey, 16.2% (between 32.6 and 35.1 million) of Americans will experience depression at some point during their lives, and 6.6% (between 13.1 and 14.2 million) are depressed in any given month.[4,5] Several epidemiological studies reported that up to 8.3% of adolescents in the United States suffer from depression.[6] Older adolescents experience more depressive symptoms than adults and comparable symptom persistence, suggesting that these adolescents may be at the highest risk for depression.[7]

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Depression can take several forms: three of the most common are dysthymia, major depression, and bipolar disorder.[2] These three disorders are characterized by various combinations of the symptoms listed in Table 1. Not every patient exhibits all depressive symptoms. Some patients, especially adolescents, may display irritability instead of sadness.

TABLE 1. Symptoms of depression

- Persistent sad, anxious, or "empty" mood
- Feelings of hopelessness, pessimism
- Feelings of guilt, worthlessness, helplessness
- Irritability, restlessness
- Loss of interest in activities or hobbies once pleasurable including sex
- Fatigue or decreased energy being "slowed down"
- Difficulty concentrating, remembering details, and making decisions
- Insomnia, early-morning wakefulness, or excessive sleeping
- Overeating, or appetite loss
- Thoughts of suicide, suicide attempts
- Aches or pains, headaches, cramps, or digestive problems that do not ease even with treatment.

Table 1 modified from National Institutes of Health. "What is Depression?" Available at: http://www.nimh.nih.gov/health/publications/depression/index.shtml. Accessed September 8, 2014

Dysthymia has characteristics similar to those of major depression but is not as disabling. People with dysthymia often function adequately but not at previous wellness levels, and are at risk for episodes of major depression. In major depression, a combination of symptoms prevents the patient from working, studying, and/or engaging in normal activities.

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In bipolar disorder, the patient alternates between periods of depression (severe lows) and episodes of mania (severe highs).[2]

Symptoms of mania[2]

- Abnormal or excessive elation
- Unusual irritability
- Decreased need for sleep
- Grandiose notions
- Increased talking
- Racing thoughts
- Increased sexual desire
- Markedly increased energy
- Poor judgment
- Inappropriate social behavior

Causes of depression

The causes of depression are often multifactorial and may include:

- Genetic predisposition[2]
- Stress at home, work, or school[2]
- Loss of a parent or loved one[8]
- Alcohol or substance abuse[9]
- Breakup of a romantic relationship[10]
- Medications[11]

Suicide

Suicide accounts for more than 30,000 American deaths each year. It is the third leading cause of death (after accidents and homicide) among people aged 15 to 24, which makes it responsible for more deaths in this age group than any physical illness.[12–14] Of the total number of suicides among people ages 15 to 24 in 2001, 86% were male and 14% were female.[15, 16] Healthcare providers often miss the warning signs because patients may hide suicidal intent very successfully. In fact, 60% of people who commit suicide had seen a physician within 1 month of their deaths.[9] Suicidal tendencies rarely arise spontaneously; 93% of people who commit suicide suffer from depression, schizophrenia, and/or substance abuse.[17]

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Up to 60% of adolescents and young adults think about suicide at some point,[12] but fortunately these thoughts usually pass. Few people who have suicidal thoughts make the attempt, and most attempts at suicide are unsuccessful.[13] The following are some elements of a suicide risk assessment that can be used to determine the individual's risk level for suicide[18]:

- Ideation (thoughts of death or suicide)
- Suicidal intent
- Plan (specific time, place, and method)
- Means (e.g., a firearm in the house or a supply of drugs)

Women are twice as likely as men to attempt suicide, but men are four times more likely to be successful. Women usually use means from which they may be rescued, such as a drug overdose,[19] whereas men tend to use firearms or automobiles. Firearms are used in 55% of all completed suicides.[13]

Despite a patient's attempt to hide suicidal thoughts, he or she may send deliberate warning signals, some of which can be explicit.[2] Every mention or discussion of "killing myself" should be treated with utmost seriousness.

Evaluating And Referring Patients For Psychiatric Disorders

Although only 5% of the population is depressed at any given time,[20] the incidence has been found to be closer to 15% to 20% in primary care settings.[21] Given that 1 in 5 patients who come to your office may have some degree of depression, a few questions can identify patients who may be at risk.

It is important to find out whether a patient is under care or has ever been under care for an emotional problem or psychiatric disorder, particularly depression. Knowing a patient's current medications, for example, if he or she is taking antidepressants, can further identify those patients who may be at even greater risk than the general population.

Talking About Depression

Although it can be awkward to explain to a patient that he or she may have signs of depression (or any mental illness), the awkwardness can be minimized by reminding the patient that:

- Depression is very common
- It matches some of the symptoms the patient described
- It is treatable

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Assessments: Depression

While taking a history, the prescriber should suspect the likelihood of depression if the patient has symptoms such as[6]:

- Persistent sad or irritable mood
- Loss of interest in activities once enjoyed
- Significant change in appetite or body weight
- Difficulty sleeping or oversleeping
- Psychomotor agitation or retardation
- Loss of energy
- Feelings of worthlessness or inappropriate guilt
- Difficulty concentrating
- Recurrent thoughts of death or suicide

In children and young adolescents, other signs to look for include[6]:

- Frequent, vague, non-specific physical complaints such as headaches, muscle aches, stomach aches, or tiredness
- Frequent absences from school or poor performance in school
- Talk of or efforts to run away from home
- Outbursts of shouting, complaining, unexplained irritability, or crying
- Being bored
- Lack of interest in playing with friends
- Alcohol or substance abuse
- Social isolation, poor communication
- Fear of death
- Extreme sensitivity to rejection or failure
- Increased irritability, anger, or hostility
- Reckless behavior
- Difficulty with relationships

The prescriber should also discuss with the patient:

- Alcohol or substance abuse
- Chronic pain
- Real or perceived disfigurement

Studies indicate that acne is associated with symptoms such as social embarrassment, low self-esteem, and anxiety, but an association of acne with frank depressive disorders has not been established, nor has treatment of acne by itself been shown to ameliorate frank depressive disorders.[22-24]

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Assessments: Suicide

Psychiatric specialists have identified several factors for suicide risk. These include[19]:

- Presence or history of depression, bipolar disorder, or other psychiatric disorder
- Access to firearms in the home
- Family history of suicide or violence, including abuse
- Poor physical health, chronic illness, or chronic pain
- Alcohol or substance abuse
- Previous suicide attempt

It is important to note that depression itself is a major risk factor for suicidal behavior.[19] Thus, special attention is needed when prescribing drugs that may cause depression. An association with isotretinoin should be considered in patients with signs and symptoms of depression, even in the presence of other life stressors. Discontinuation of isotretinoin may be insufficient intervention and a formal psychiatric evaluation should be conducted. It is also important to note that signs and symptoms of depression are not included in all reported cases of suicidal behavior. It is not known if this means the signs were masked by the patient, unrecognized by observers, or if the suicidal tendency arose impulsively. It is important that patients taking isotretinoin be made aware of this so that they might recognize any such signs and symptoms. Patients (and parents, if the patient is a minor) should be instructed to stop isotretinoin and seek immediate medical help.

Talking with patients about suicide does not encourage or remind them that suicide is an option.[19]

Knowing When To Refer

You should refer the patient to a psychiatric specialist for further evaluation if any of the following apply:

- Risk factor(s) for suicide is (are) present
- The patient has, or may have, clinical depression or bipolar disorder, or if the prescriber believes that there may be a problem but cannot classify it
- The patient has expressed interest in, or spontaneously mentioned, suicide
- There is any question about the patient's safety

Summary

Prescribers who are alert to the warning signs of psychiatric disorders can guide patients to receive the help they need. Observing patients for signs of depression and suicidal ideation, and referring appropriate patients to a psychiatric specialist, need not be complicated. The benefits to patients can be immense, even life saving.

National Suicide Prevention Lifeline
1-800-273-8255
http://www.suicidepreventionlifeline.org/

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Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

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Most Recent Modification: July 2016

The iPLEDGE Program

The Guide To Best Practices For the iPLEDGE Program

The resource to help the prescriber prepare, plan treatments, and prevent pregnancies during the course of isotretinoin therapy

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

Committed to Pregnancy Prevention

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The Guide To Best Practices For the iPLEDGE Program

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Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. In addition, for female patients of reproductive potential, isotretinoin is indicated only for those female patients who are not pregnant (see boxed CONTRAINDICATIONS AND WARNINGS and PRECAUTIONS sections).

Important Facts About Isotretinoin

- Isotretinoin is highly teratogenic.
- Treatment with isotretinoin during pregnancy is contraindicated. Female patients should not be pregnant or become pregnant while on isotretinoin therapy and for 1 month thereafter.
- Fetal exposure to isotretinoin may result in life-threatening congenital abnormalities.

The Guide To Best Practices For the iPLEDGE Program

This guide has been developed to assist you in fulfilling the requirements for isotretinoin pregnancy prevention risk management. Please refer to the CONTRAINDICATIONS AND WARNINGS and the PRECAUTIONS sections of the isotretinoin Package Insert.

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see **PRECAUTIONS**).

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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ABOUT ISOTRETINOIN

Isotretinoin is used to treat severe recalcitrant nodular acne. Isotretinoin belongs to a class of drugs known as retinoids, commonly understood to include all natural and synthetic analogues of vitamin A. Therapy with isotretinoin should not be undertaken before conventional treatment has been tried first, including the use of systemic antibiotic therapy, and the patient has been fully counseled about the warnings and precautions in the isotretinoin package insert.

Isotretinoin is teratogenic and must not be used by pregnant women. Women should not become pregnant while taking isotretinoin or for 1 month after therapy is discontinued. A patient who becomes pregnant during treatment should stop taking isotretinoin and immediately contact her prescriber.

Isotretinoin use is associated with other potentially serious adverse events as well as more frequent, but less serious side effects. More frequent, less serious side effects include cheilitis, dry skin, skin fragility, pruritus, epistaxis, dry nose and dry mouth, and conjunctivitis.

Serious Adverse Event Warnings include psychiatric disorders* (depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors). Prescribers should read the brochure *Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of Isotretinoin therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary.

Other Serious Adverse Event Warnings include; pseudotumor cerebri; pancreatitis; hyperlipidemia; hearing impairment*; hepatotoxicity; inflammatory bowel disease; skeletal changes† (bone mineral density changes, hyperostosis, premature epiphyseal closure); and visual impairment (corneal opacities, decreased night vision).

Patients should be reminded to read the Medication Guide, distributed by the pharmacist at the time the isotretinoin is dispensed.

Pregnancy After Isotretinoin Therapy

The terminal elimination half-life of isotretinoin varies but is generally within 10 to 20 hours. The elimination half-life of one of the isotretinoin metabolites, 4-oxoisotretinoin, is approximately 25 hours. Since plasma elimination is host dependent, prescribers should warn patients not to become pregnant for 1 month post-treatment. Women who become pregnant during this month should be counseled as to the outcome data. In 1989, Dai et al reported the results of an epidemiologic study of pregnancies that occurred in women who conceived after discontinuing isotretinoin.[1] They studied women from 5 days to more than 60 days between the last dose of isotretinoin and conception. The incidence of birth defects in former isotretinoin patients was not significantly different from the rate in the general population.

* No mechanism of action has been established for these events.

† The use of isotretinoin in patients ages 12 to 17 should be given careful consideration especially when a known metabolic or structural bone disease exists.

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Isotretinoin is found in the semen of male patients taking isotretinoin, but the amount delivered to a female partner would be about 1 million times lower than an oral dose of 40 mg. While the no-effect limit for isotretinoin-induced embryopathy is unknown, 20 years of post-marketing reports include 4 with isolated defects compatible with features of retinoid-exposed fetuses; however, 2 of these reports were incomplete, and 2 had other possible explanations for the defects observed.

Birth Defects

There is an extremely high risk that a deformed infant will result if pregnancy occurs while female patients are taking isotretinoin in any amount even for short periods of time. Potentially, any fetus exposed during pregnancy can be affected. Not every fetus exposed to isotretinoin has resulted in a deformed child. However, there are no accurate means of determining which fetus has been affected and which fetus has not been affected.

When isotretinoin is taken during pregnancy, it has been associated with fetal malformations, and there is an increased risk for spontaneous abortions and premature birth. **The following human fetal abnormalities have been documented.**

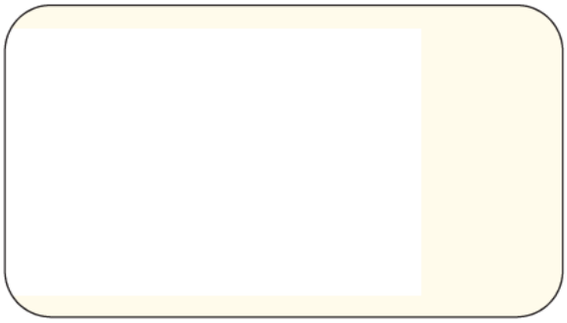
External abnormalities

Skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate.

Internal abnormalities

CNS abnormalities including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit; cardiovascular abnormalities; thymus gland abnormalities; parathyroid hormone deficiencies. In some cases death has occurred with certain of the abnormalities noted.

Line drawing represents the possible abnormalities of the low-set, deformed, or absent ears; wide-set eyes; depressed bridge of nose; enlarged head; and small chin.



Line drawing represents the possible abnormalities of the brain, heart, and thymus gland that may occur.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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THE iPLEDGE PROGRAM

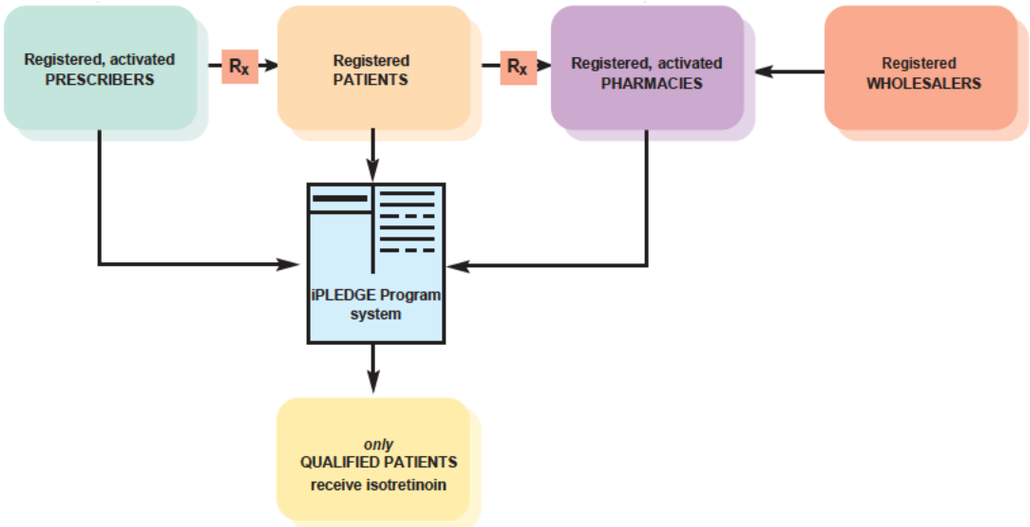
Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE. The iPLEDGE Program is a single, shared Risk Evaluation and Mitigation Strategy (REMS) program for prescribing and dispensing all isotretinoin products (brand and generic products) and includes a pregnancy registry.

Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see PRECAUTIONS).

The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions.

The iPLEDGE Program employs a computer-based risk management system that uses verifiable, trackable links between prescriber, patient, pharmacy, and wholesaler to control prescribing, using, dispensing, and distribution of isotretinoin.

The trackable links of the iPLEDGE Program



Key Features Of The iPLEDGE Program

The iPLEDGE Program has specific requirements for prescribers, patients, pharmacists, and wholesalers. Here is an overview:

- The iPLEDGE system tracks and verifies critical program elements that control access to isotretinoin.
- Only prescribers registered with and activated in the iPLEDGE Program can prescribe isotretinoin.
- Prescribers or their office designee must enter required information (pregnancy test results, 2 forms of contraception used, confirmation of patient counseling) in the iPLEDGE system for patients to be qualified to receive a prescription after the patient correctly answers a few comprehension questions..
- Prescribers must document that all patients—and specifically females of reproductive potential—meet the requirements in the iPLEDGE Program.

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- Only patients who are registered by prescribers in the iPLEDGE Program can receive isotretinoin.
- Females of reproductive potential must enter required information (2 forms of contraception used, answer questions on program requirements) in the iPLEDGE Program system in order to be qualified to receive a prescription.
- Only pharmacies registered with and activated in the iPLEDGE Program can dispense isotretinoin.
- Pharmacists must access the iPLEDGE Program system to receive authorization to fill and dispense every isotretinoin prescription.
- Telephone, fax, and electronic transmission (e.g., e-mail) prescriptions are permitted in the iPLEDGE Program.
- Manufacturers will only ship isotretinoin to iPLEDGE Program-registered entities (e.g., direct vendor pharmacies, wholesalers).
- Wholesalers must register annually in the iPLEDGE Program. A registered wholesaler may distribute only FDA-approved isotretinoin product.
- Only wholesalers registered with the iPLEDGE Program can distribute isotretinoin.
- Registered wholesalers can only ship isotretinoin to wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer or pharmacies licensed in the US and registered and activated in the iPLEDGE Program.

Non-Compliance Action Policy (NCAP)

The Non-Compliance Action Policy was implemented to monitor compliance, address deviations, and institute appropriate corrective actions to improve minimization of drug exposure during pregnancy and compliance with elements to assure safe use under the iPLEDGE Program. The NCAP sets forth the principles by which Non-Compliance by iPLEDGE Program stakeholders will be evaluated. The NCAP can be found on the iPLEDGE Program website at www.ipledgeprogram.com

KEY INFORMATION FOR PRESCRIBERS

Prescribers need to follow the key points of the iPLEDGE Program. These points are explained in detail in *The Guide To Best Practices For the iPLEDGE Program*. The key areas the prescriber must understand include:

The Non-Compliance Action Policy (NCAP)

- The iPLEDGE Program educational materials for prescribers and patients
- Activation in the iPLEDGE Program automated system
- Prescriber steps required "Before," "During," and "After" treatment with isotretinoin
- Specific program criteria and procedures for females of reproductive potential
- Education for all patients about isotretinoin and the iPLEDGE Program requirements
- Patient registration
- The initial and monthly procedures for prescribing isotretinoin and information on the requirements for pharmacists
- Information on what to do in the event of a pregnancy
- Prescriber delegates and office staff designees

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS .**

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THE iPLEDGE WEB SITE AND PHONE SYSTEM

The prescriber can access the iPLEDGE Program system via the program web site and automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The automated system is used to:

- Activate registration
- Register patients
- Confirm patient counseling monthly for all patients for each prescription
- Enter monthly pregnancy test results and contraception information for females of reproductive potential. **The patient cannot answer her monthly questions until the prescriber has entered the pregnancy test results in the iPLEDGE Program system.**
- Track the current status of a patient.
- Order additional copies of *The Guide To Best Practices For the iPLEDGE Program* and of patient and professional educational materials
- Manage delegates and designate office staff
- Find a participating pharmacy
- Enter and make changes to patient name, address, phone number and date of birth.
- Edit prescriber name, specialty, address, phone and fax numbers, e-mail address and preferred method of communication (US Mail or e-mail)

Logging in to either the web site or phone system requires a username and password, which are supplied upon registration.

To review and order materials

You can order additional program materials using either the web site or the phone system as follows:

1. After logging on to the web site, there are two ways to order materials:
   a. Using the navigation menu on the left side of the page, select the "Order Materials" button.

      OR

   b. Using the navigation menu on the left side of the page choose "Prescriber Information". In the "View Information Online" section, Select "To Order Educational Materials, please click here".
2. In the phone system, log in and select the option to "Request Program Information."

Materials will be shipped via ground delivery, and should arrive in 5 to 7 business days. The prescriber address in the iPLEDGE Program at the time of the order will be used for the shipping destination. This address can be changed by the user as needed to direct shipments to specific desired locations.

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PROGRAM MATERIALS

The iPLEDGE Program provides educational materials for prescribers and patients. There is also a guide for pharmacists.

Prescriber Materials

It is important that the prescriber reviews the materials in the educational kit.

1. *The Guide To Best Practices For the iPLEDGE Program* describes the requirements of the iPLEDGE Program for prescribers and for male and female patients.
2. *The iPLEDGE Program Prescriber Contraception Counseling Guide* is an overview of the effective forms of contraception and is a companion to the patient *iPLEDGE Program Birth Control Workbook*.
3. The brochure *Recognizing Psychiatric Disorders In Adolescents And Young Adults* contains important information about depression, suicide, and psychiatric assessment and referral of your patients.

Additional materials

Additional resource materials can be viewed on the iPLEDGE Program web site. These include:

- Isotretinoin Medication Guide
- Isotretinoin Package Inserts
- Prescribing Checklists
- Isotretinoin Contraception Referral Form
- Prescriber Activation Instructions
- Instructions for Registering and Managing Office Staff Designees
- Patient and Prescriber Flowcharts
- FAQ's (Frequently Asked Questions)

Patient Materials

The prescriber distributes *The iPLEDGE Program Patient Introductory Brochure* to patients considering taking isotretinoin. A patient educational kit, which provides information about the iPLEDGE Program requirements, should be given to the patient when they are registered in the iPLEDGE Program.

All kits include:

- The appropriate patient guide—*The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant or The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant*

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

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- The Patient Information/Informed Consent (for all patients) form
- The patient ID card and number

Additionally, the kit for females of reproductive potential includes:

- *The iPLEDGE Program Birth Control Workbook*. This provides in-depth information about effective forms of contraception with iPLEDGE and their optimal use.
- *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. This includes the form to refer your patient to a contraception expert for counseling and a guide for the counselor about the requirements of the iPLEDGE Program.
- The Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.

Educational Video

The prescriber educational kit also includes educational materials for patients with two videos: ***Be Prepared, Be Protected*** and ***Be Aware: The Risk of Pregnancy While on Isotretinoin.*** These describe the kind of birth defects that may happen if a woman takes any amount of isotretinoin while she is pregnant and also review reasons for contraception failure.

ACTIVATING REGISTRATION

iPLEDGE registration must be activated in the iPLEDGE Program system before a prescriber can prescribe isotretinoin. Activation must occur annually.

The iPLEDGE Program system will report the expiration date of the prescriber's activation. To retrieve this information, the prescriber:

- On the web site, logs in and chooses "My Program Status" on the left navigation
- In the phone system, logs in and selects the option to hear "Program Status"

The prescriber should review *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide* to understand the program. Activation requires the prescriber to attest to the following statements in the iPLEDGE Program system:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I know the risk factors for unplanned pregnancy and the effective measures for avoidance of unplanned pregnancy.
- I have the expertise to provide the patient with detailed pregnancy prevention counseling or I will refer her to an expert for such counseling, reimbursed by the manufacturer.
- I will comply with the iPLEDGE Program requirements described in the booklets entitled *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide*.

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- Before beginning treatment of females of reproductive potential with isotretinoin, and on a monthly basis, the patient will be counseled to avoid pregnancy by using 2 forms of contraception simultaneously and continuously 1 month before, during, and 1 month after isotretinoin therapy, unless the patient commits to continuous abstinence.
- I will not prescribe isotretinoin to any female of reproductive potential until verifying she has a negative screening pregnancy test and monthly negative CLIA-certified (Clinical Laboratory Improvement Amendment) pregnancy tests. Patients should have a pregnancy test at the completion of the entire course of isotretinoin and another pregnancy test 1 month later.
- I will report any pregnancy case that I become aware of while the female patient is on isotretinoin or 1 month after the last dose to the pregnancy registry.

Procedures For Activating In The iPLEDGE System

The prescriber can access the iPLEDGE Program system to activate registration via the web site, **www.ipledgeprogram.com**, or the automated phone system, **1-866-495-0654.** The web site is the faster and easier way to access the system. Identification in either system requires the username (DEA number or program-generated user-name) and password received with the registration materials. For information on the internet browsers compatible with the iPLEDGE Program web system, consult the FAQ's on the home page of the site, www.ipledgeprogram.com.

The system requires setting the prescriber's Date of Personal Significance. This is a date that the prescriber will be able to easily remember. It will be used to verify prescriber identity if needed by the iPLEDGE Program system or if a password is lost.

After initial activation, a prescriber must re-activate at least annually to remain active in the iPLEDGE Program. The iPLEDGE Program system will display the "Activate" button on the Prescriber home page when the activation for a prescriber is nearing expiration. However, a prescriber can re-activate at any time using the "Prescriber Activation" button on the left-hand navigation menu on all pages.

Using the web site

The prescriber:

1. Logs in by entering username (DEA number or program-generated username) and password.
   - The system will provide prompts to change the prescriber's password and set the prescriber's Date of Personal Significance.
2. On the Prescriber home page, select "Activate My Registration". **The system will provide prompts to complete the activation process.** If your current activation is nearing expiration, the Prescriber home page will prominently display a direct link to re-activate.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Using the phone system

The prescriber:

1. Logs in and follows the prompts.
   - The system will provide prompts to change the prescriber's password and set the prescriber's Date of Personal Significance.
2. Selects the option to "Activate Your Registration." The system will provide prompts to complete the activation process.

OVERVIEW: PROGRAM REQUIREMENTS

The iPLEDGE Program has specific requirements for prescribers, patients, and pharmacists. One of the prescriber's main responsibilities is knowing and educating patients about these requirements.

Prescribers are responsible for registering every patient, who meets the program requirements, in the iPLEDGE Program via the automated system. They are responsible for educating patients about the side effects of isotretinoin and the high risk of birth defects for females of reproductive potential while taking the drug. As part of this process, they are also responsible for counseling patients about the monthly steps they must follow to receive isotretinoin.

Prescribers can only write a patient's prescription for isotretinoin for up to a maximum of a 30-day supply. Patients must plan for monthly appointments to receive their prescriptions. At each of these appointments, the prescriber must counsel the patient about the iPLEDGE Program requirements and then confirm via the iPLEDGE automated system that this counseling occurred.

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient, as follows:

Female patients who can get pregnant…	Male patients and female patients who cannot get pregnant…
The prescription window is 7 days, and starts on the date that the urine or blood sample is taken for a pregnancy test. This date is counted as DAY 1. To determine the end date of their 7-day prescription window, these patients should add 6 days to the date of the blood or urine sample being taken.	The prescription window is 30 days, and starts on the date the prescriber enters as the date of the office visit. This date is counted as DAY 1. To determine the end date of their 30-day prescription window, these patients should add 29 days to the date of their office visit.

After 11:59 p.m. Eastern Time on the last day of the prescription window, the patient can no longer fill and pick up their prescription, and must start the process over to get a new prescription window*

*There are generally no restrictions regarding the timing of office visits. One notable exception is that females of reproductive potential who do not obtain their first month of therapy prescription in their first 7-day prescription window, must wait at least 19 days from their most recent pregnancy test until getting their next pregnancy test. This is based on the requirement that the most recent pregnancy test prior to beginning therapy must be conducted in the first 5 days of her menstrual cycle.

There are different program requirements for male patients and females of non-reproductive potential and for females of reproductive potential..

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The prescriber must determine if a patient is a female of reproductive potential (see page 18) and document that she meets the specific requirements of the program. These include taking pregnancy tests and using 2 forms of birth control consistently. Both of these requirements must be followed before, during, and after treatment.

To receive monthly prescriptions, a female of reproductive potential must also answer questions in the iPLEDGE Program system about the program requirements and pregnancy prevention. **Answering these questions can only take place after the prescriber has confirmed counseling, and entered the pregnancy test result and the patient's 2 forms of contraception (or reliance on abstinence) into the system.** In addition to answering the questions, the patient must also enter the 2 forms of birth control she is using (or indicate that she is relying on abstinence).

The pregnancy test can be obtained prior to, at the time of, or after the office visit. **However, the 7-day prescription window will begin with the date that the specimen draw was performed.**

These are the criteria the system uses to authorize a pharmacy to fill and dispense a prescription.

The Guide To Best Practices For the iPLEDGE Program includes a checklist of steps to follow before, during, and after patient treatment. *(see page 15)*

Below are the main requirements for patients and pharmacists.

Requirements For All Patients

To receive isotretinoin, all patients must meet all of the following conditions:

1. ***Must*** be registered with the iPLEDGE Program by the prescriber
2. ***Must*** understand that severe birth defects can occur with the use of isotretinoin by female patients
3. ***Must*** be reliable in understanding and carrying out instructions
4. ***Must*** sign a Patient Information/Informed Consent (for all patients) form that contains warnings about the potential risks associated with isotretinoin
5. ***Must*** obtain the prescription within the prescription window defined as follows:
   - Male patients and female patients who cannot get pregnant must obtain their prescription within the 30-day prescription window, counting the office visit as DAY 1.
   - Female patients who can get pregnant must obtain their prescription within 7 days of their pregnancy test, which is determined by the date of the blood draw or urine sample used in the test. The pregnancy test can be obtained before, during or after the office visit.

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6. ***Must*** not donate blood while on isotretinoin and for 1 month after treatment has ended

7. ***Must*** not share isotretinoin with anyone, even someone who has similar symptoms

All patients should understand that refills are not allowed. Patients can only receive a maximum of a 30-day supply of isotretinoin per prescription. For each prescription, continuation of therapy requires the patient to satisfy the iPLEDGE Program requirements to obtain a new prescription. The prescriber must also counsel the patient monthly about the iPLEDGE Program requirements and then confirm via the iPLEDGE Program system that this counseling occurred.

Females of reproductive potential must:

- Have an initial pregnancy test, which may be performed in the prescriber's office
- Be counseled on contraception requirements
- Use 2 forms of contraception together for sexual intercourse for 1 month before, during, and for 1 month after treatment with isotretinoin
- There is a 30-day mandatory waiting period during which females of reproductive potential must be using both chosen forms of birth control simultaneously before they are eligible to begin treatment with isotretinoin.
- Have a second pregnancy test within the first 5 days of the menstrual cycle, performed in a CLIA-certified laboratory, after being on 2 effective forms of contraception for 1 month and before starting isotretinoin therapy.* This second pregnancy test must be at least 19 days after the initial pregnancy test.
- Fulfill monthly requirements before receiving each prescription:
  - Have a serum or urine pregnancy test performed in a CLIA-certified laboratory*
  - Access the system to answer questions about the iPLEDGE Program requirements and pregnancy prevention
  - Enter into the iPLEDGE Program system the 2 forms of contraception being used
- Have a pregnancy test after their last dose, performed in a CLIA-certified laboratory
- Continue using 2 forms of contraception for 1 month after their last dose
- Have a pregnancy test 1 month after their last dose

About the patient questions

Prior to being able to obtain a prescription, females of reproductive potential ***must*** answer questions about the iPLEDGE Program and pregnancy prevention. **These questions must be answered after their prescriber has confirmed counseling, entered pregnancy test results and 2 contraceptive methods (or reliance upon abstinence) into the iPLEDGE Program system, but before the 7-day prescription window for their prescription expires.** Patients answer these questions via the web site or phone system. (Access information is provided in the patient guide.) The patient may use her patient guide and *The iPLEDGE Program Birth Control Workbook* to help with the answers.

* For timing information about monthly pregnancy tests, see number 1 on page 19 under "Qualification criteria for females of reproductive potential"

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The system provides questions in several specific categories and correct answers for those questions, with references to the appropriate patient education material. A replacement question in the same category is provided for an incorrectly answered question.

If a patient misses a replacement question, the iPLEDGE Program system will direct her to review her materials and try again at a later time. She may also contact her prescriber so that her program education and counseling can be reinforced. The patient should also review her educational materials and then answer the question again.

Requirements For Pharmacists

- Isotretinoin can only be obtained from pharmacies registered with and activated in the iPLEDGE Program.
- Registered and activated pharmacies can obtain isotretinoin only from wholesalers registered with the iPLEDGE Program.
- **The dispensing pharmacist must obtain authorization and a Risk Management Authorization (RMA) number** before filling and dispensing prescriptions.
- **Upon receiving authorization, the dispensing pharmacist can fill and dispense a prescription** for a maximum 30-day supply of isotretinoin.
- **Upon authorization, the iPLEDGE Program system** provides the RMA number to the dispensing pharmacist. The pharmacist should document the RMA number.
- **Upon authorization, the iPLEDGE Program system** provides a "**Do Not Dispense To Patient After**" date to the dispensing pharmacist. This date is calculated as 30 days from the office visit for male patients and females of non-reproductive potential, or 7 days from the pregnancy test date for females of reproductive potential. The pharmacist should record this date on the prescription bag sticker.
- **The iPLEDGE Program system** only authorizes filling and dispensing prescriptions when patients have met the qualification criteria in the system.
- **Prescriptions** that are more than 30 days beyond the date of the office visit (for male patients and females of non-reproductive potential) or more than 7 days beyond the pregnancy test date (for females of reproductive potential), will not be authorized by the iPLEDGE Program system.
- Prescriptions must be obtained no later than the "Do Not Dispense To Patient After" date, and if not obtained, then the RMA must be reversed in the iPLEDGE Program system and the product returned to inventory.
- **No automatic refills** are permitted.
- **Isotretinoin** comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.
- An isotretinoin Medication Guide must be given to the patient each time isotretinoin is dispensed, as required by law.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

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Pharmacy Information

Patients can only obtain isotretinoin prescriptions from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com**, provides a database of registered pharmacies. Patients and prescribers can access this information by logging in and choosing the "Find a Participating Pharmacy" button on their home page.

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

iPLEDGE PROGRAM PRESCRIBING CHECKLISTS

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient, as follows:

Female patients who can get pregnant…	Male patients and female patients who cannot get pregnant…
The prescription window is 7 days, and starts on the date that the urine or blood sample is taken for a pregnancy test. This date is counted as DAY 1. To determine the end date of their 7-day prescription window, these patients should add 6 days to the date of the blood or urine sample being taken.	The prescription window is 30 days, and starts on the date the prescriber enters as the date of the office visit. This date is counted as DAY 1. To determine the end date of their 30-day prescription window, these patients should add 29 days to the date of their office visit.

After 11:59 p.m. Eastern Time on the last day of the prescription window, the patient can no longer fill and pick up their prescription, and must start the process over to get a new prescription window*

*There are generally no restrictions regarding the timing of office visits. One notable exception is that females of reproductive potential who do not obtain their first month of therapy prescription in their first 7-day prescription window, must wait at least 19 days from their most recent pregnancy test until getting their next pregnancy test. This is based on the requirement that the most recent pregnancy test prior to beginning therapy must be conducted in the first 5 days of her menstrual cycle.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.** 6/4/12 1 29 PM

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Females Of Reproductive Potential

Before

PLANNING

- ❑ **Plan** for office visits, counseling, pregnancy testing.
- ❑ **Educate** about isotretinoin and the contraception requirements of the iPLEDGE Program.
- ❑ **Screen** with serum or urine pregnancy test, which may be performed in the prescriber's office: must be negative for patient to enter the iPLEDGE Program system.
- ❑ **Obtain** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Register** patient in the iPLEDGE Program system and provide patient with an educational kit, which includes the Patient ID number on perforated, removable cards.

COUNSEL ON CONTRACEPTION

- ❑ Counsel patient in office or refer to healthcare professional with expertise in contraception. Please see page 22 for information on referring for contraception counseling.
- ❑ **Counsel** patient that she must use 2 effective forms of contraception simultaneously for at least 1 month before starting therapy. There is a 30-day mandatory waiting period during which she must be using both chosen forms of birth control before she is eligible to begin treatment with isotretinoin.
- ❑ **Inform** patient about confidential iPLEDGE Program Pregnancy Registry.

PRESCRIBE

- ❑ Verify female patient qualification criteria.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory:
  - During the first 5 days of the menstrual cycle, OR
  - For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month. Please refer to the section on. "Qualification criteria for females of reproductive potential" (*see page 19*) for details on the timing of this test.
- ❑ **Obtain** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system within the 7-day prescription window, counting the date of specimen collection for the pregnancy test as DAY 1. Your patient will not be able to answer her comprehension questions and then obtain her prescription until you have completed this task.

During
(at each monthly visit)

- ❑ **Counsel** patient on contraception adherence.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system within the 7-day prescription window, counting the date of specimen collection for the pregnancy test as DAY 1. Your patient will not be able to answer her comprehension questions and then obtain her prescription until you have completed this task.

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After

AFTER THE LAST DOSE

- ❑ **Counsel** patient on contraception adherence for 30 more days.
- ❑ **Counsel** patient not to give blood for at least 1 month after the last dose.
- ❑ **Order** a pregnancy test using a CLIA-certified laboratory after the last dose.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system.
  - If you do not enter the results of the pregnancy test at the conclusion of therapy, the patient will be classified as Lost to Follow Up, and both you and the patient may be contacted for additional information.

1 MONTH AFTER THE LAST DOSE

- ❑ **Order** a pregnancy test using a CLIA-certified laboratory.
- ❑ **Enter** pregnancy test results and the patient's 2 forms of contraception in the iPLEDGE Program system.
  - If you do not enter the results of the pregnancy test 1 month after the conclusion of therapy, the patient will be classified as Lost to Follow Up, and both you and the patient may be contacted for additional information.

Refer to page 27 for information about reporting pregnancies to the confidential iPLEDGE Program Pregnancy Registry.

Male Patients And Female Patients Who Cannot Get Pregnant

Before

PLANNING

- ❑ **Plan** for monthly office visits.
- ❑ **Educate** patients about isotretinoin and the iPLEDGE Program.
- ❑ **Obtain** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Register** patients in the iPLEDGE Program system and provide patient with an educational kit, which includes the Patient ID number on perforated, removable cards.

PRESCRIBE

- ❑ **Confirm** patient counseling about program requirements in the iPLEDGE Program system within the 30-day prescription window, counting the patient's office visit as DAY 1. The patient will not be able to obtain his/her prescription until you have completed this task.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.

During
(at each monthly visit)

- ❑ **Counsel** patient on program adherence.
- ❑ **Confirm** patient counseling of program requirements in the iPLEDGE Program system within the 30-day prescription window, counting the patient's office visit as DAY 1. The patient will not be able to obtain his/her prescription until you have completed this task.
- ❑ **Provide** a prescription for up to a maximum 30-day supply of isotretinoin.

After

AFTER THE LAST DOSE

- ❑ **Counsel** patient not to give blood for at least 1 month after the last dose.

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DETERMINE REPRODUCTIVE POTENTIAL OF FEMALE PATIENTS

Qualification Criteria

The prescriber must determine if a female is of reproductive potential before enrolling her in the iPLEDGE Program. The definition of a female of reproductive potential is a nonmenopausal female who has not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure. This definition includes a young woman who has not yet started menstruating.

- A woman who has had a tubal sterilization is considered a female of reproductive potential in the iPLEDGE Program.

Definition of menopause

Menopause can be assumed to have occurred in a woman when there is either:

1. Appropriate medical documentation of prior complete bilateral oophorectomy (i.e., surgical removal of the ovaries, resulting in "surgical menopause" and occurring at the age at which the procedure was performed), OR

2. Permanent cessation of previously occurring menses as a result of ovarian failure with documentation of **hormonal deficiency** by a certified healthcare provider (i.e., "spontaneous menopause," which occurs in the United States at a mean age of 51.5 years).

Hormonal deficiency should be properly documented in the case of suspected spontaneous menopause as follows:

1. If age >54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed;

2. If age <54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

Screen patients

Data support that there are key issues in identifying female patients for treatment with isotretinoin.

The prescriber should:

1. Identify patients whose acne could be effectively managed without isotretinoin and avoid prescribing it for such patients
2. Identify those who are already pregnant when considering isotretinoin
3. Identify those who may not be reliable in avoiding pregnancy for the required period before, during, and after therapy

The patient should understand that, ultimately, it is her responsibility to avoid exposing an unborn baby to isotretinoin. The patient must understand the critical responsibility she assumes in electing to undertake therapy with isotretinoin and that any method of birth control, apart from complete abstinence, can fail.

The prescriber must verify that each individual patient receives adequate counseling about all her pregnancy prevention options (including abstinence) and that she knows how to select and use 2 separate, effective contraceptive methods.

Qualification criteria for females of reproductive potential

Once the prescriber decides to pursue qualification of the patient, a female of reproductive potential must follow these steps.

1. Before the patient can begin isotretinoin therapy, there is a 30-day wait period where the patient must be on two forms of birth control simultaneously. Additionally, she will need to have 2 negative pregnancy tests. Femalesof reproductive potential must have had 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL before receiving the initial isotretinoin prescription. The first test (a screening test) is obtained by the prescriber when the decision is made to pursue qualification of the patient for isotretinoin. The second pregnancy test (a confirmation test) must be done in a CLIA-certified laboratory. The interval between the 2 tests must be at least 19 days.
   - For patients with regular menstrual cycles, the second pregnancy test must be done during the first 5 days of the menstrual period, immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - The patient must be using her two forms of contraception for at least 30 days prior to beginning therapy on isotretinoin, and her second pregnancy test must occur after this 30-day period is complete.
2. The patient must sign a Patient Information/Informed Consent (for all patients) form and a Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.

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3. The patient must select and commit to use 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. Patients must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy. Counseling about contraception and behaviors associated with an increased risk of pregnancy must be repeated on a monthly basis prior to issuing each prescription.

Monthly requirements

Each month of therapy, patients must have a negative result from a urine or serum pregnancy test. A pregnancy test must be repeated each month, in a CLIA-certified laboratory, prior to the female patient receiving each prescription. A pregnancy test must also be ordered at the end of therapy (after the last dose), and 1 month after the last dose. If the results of the pregnancy tests at the conclusion of therapy, and the pregnancy test 1 month after the conclusion of therapy, are not entered into the iPLEDGE system, the patient will be classified as Lost to Follow Up, and both the prescriber and the patient will be contacted for additional information. The iPLEDGE Program also requires monthly counseling about contraception and behaviors associated with an increased risk of pregnancy.

In addition to their required doctor appointments, females of reproductive potential each month must also enter their 2 effective forms of contraception in the iPLEDGE Program system and answer questions about the iPLEDGE Program and pregnancy prevention.

Effective Forms Of Contraception

Effective forms of contraception include both primary and secondary forms of contraception.

Primary forms	Secondary forms
• Tubal sterilization • Partner's vasectomy • Intrauterine device • Hormonal (combination oral contraceptives, transdermal patch, injectables, implantables, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier forms (used with or without permicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.**

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Unacceptable Forms Of Contraception Include:

- Progesterone-only "mini-pills,"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield‡

Abstinence

For this program, all females of reproductive potential must fully commit to pregnancy prevention. Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE Program who are or have been sexually active. Abstinence may be appropriate when it is a lifestyle choice (e.g., religious practice) and not just a social circumstance (e.g., not having a current partner). If, after counseling, a sexually active patient chooses abstinence without contraception, she must understand that isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program. All females of reproductive potential must receive contraception counseling.

Contraception Counseling

The prescriber must ensure that each individual patient receives adequate counseling about all her pregnancy prevention options (including abstinence) and that she knows how to select and use 2 separate, iPLEDGE Program-effective forms of contraception that will give her the lowest failure rate.

The patient must understand the critical responsibility she assumes in electing to undertake therapy with isotretinoin and that any form of birth control, apart from complete abstinence, can fail. All females of reproductive potential must read the patient *iPLEDGE Program Birth Control Workbook*.

Reinforce the message

Counseling about contraception must be repeated on a monthly basis. Approximately 30% of female patients said they did not use 2 forms of contraception, even when knowing the risks and having consented.[2] Active counseling is one of the best tools toward getting patient compliance.

When counseling patients on contraception, the prescriber should refer to *The iPLEDGE Program Prescriber Contraception Counseling Guide*, which contains an overview of issues in contraception and the effective forms of contraception in the iPLEDGE Program. It is a companion to the patient *iPLEDGE Program Birth Control Workbook*.

It is especially important to assess the patient's ability to understand her responsibilities and instructions, and to reinforce these instructions at every clinical visit. It is very important to be able to make a careful assessment of a female patient's reproductive history, contraceptive knowledge, and previous use of contraception forms. This assessment and contraceptive education should continue throughout isotretinoin treatment.

*Ortho Micronor is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception. See page 20.

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Referral for contraception counseling

Before beginning treatment, the prescriber or patient may choose referral to a healthcare professional with expertise in pregnancy prevention. The makers of isotretinoin will reimburse one visit for contraception counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The form is in the booklet; the guide outlines the contraception requirements and the effective forms of contraception of the iPLEDGE Program for the birth control expert.

The referral form should be taken to the contraception counselor by the patient or sent in advance. The form instructs the counselor to fill in the appropriate information and return it to the prescriber with the patient's contraception choices to enter into the iPLEDGE Program system. The reverse side of the form has information for the counselor on the reimbursement process.

Referring to a gynecologist

The prescriber may want to specifically refer a patient to a gynecologist for:

- An examination prior to starting oral contraceptive agents or a hormonal transdermal patch
- Insertion of an IUD or hormonal vaginal ring
- Fitting a diaphragm or a cervical cap
- More detailed explanation of contraception options

The prescriber should also ask for gynecologic consultation under the following circumstances:

- The patient's history is suggestive of polycystic ovary syndrome (Stein-Leventhal syndrome). In addition to acne she may have:
  - Excessive facial hair growth (common when acne is present)
  - Obesity
  - Amenorrhea (no menstrual period) or irregular, heavy bleeding
  - Anovulation
- The patient has irregular menses, possibly related to pregnancy; an eating disorder; or endometriosis. It is important that the prescriber weighs the patient if there is suspicion of a potential eating disorder. Patients with eating disorders may:
  - Not admit to the problem
  - Be very underweight
- There are indications of sexual abuse found during the physical examination or counseling session.
- There is history or are symptoms of sexually transmitted infection.

Confidential birth control information

The iPLEDGE Program has automated confidential birth control information that patients can use 24 hours a day, 7 days a week. Patients can call the program's toll-free number **1-866-495-0654** and obtain information on a variety of subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

This is also a good option for patients who are vision impaired. Patients are always referred to their prescribers for additional information and clarification.

iPLEDGE PROGRAM PRESCRIBING INFORMATION

Register Patients In The iPLEDGE Program System

Patients may be registered in the iPLEDGE Program system either via the web site or phone system after obtaining the Patient Information/Informed Consent (for all patients) form and providing the patient with an ID number and ID card. The process is faster and easier using the web site.

On the web site, the prescriber logs in and chooses "Register New Patient." In the phone system, the prescriber logs in and selects the option to "Register a New Patient."

The system will request this specific patient information:

- Patient ID number
- Patient first and last name and middle initial
- Home address
- Phone number
- Date of birth
- Gender
- Last four digits of the Social Security number
- Female of reproductive potential (Yes or No)
- Screening pregnancy test date and results

ID number and ID card

The ID number and perforated ID cards are provided with the patient education materials. It is important that patients do not lose the cards. Prescribers should keep a record of the patient's number.

- All patients need the ID number and ID card to obtain their prescriptions, and to access the web site or automated phone line.
- Females of reproductive potential will need their ID number to access the iPLEDGE Program system to answer questions about the iPLEDGE Program and preventing pregnancy.

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Informed consents

Patients will need to sign the following consent forms to be in the iPLEDGE Program.

- Patient Information/Informed Consent (for all patients)
- Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)

For females of reproductive potential, signing the Patient Information/ Informed Consent About Birth Defects (for female patients who can get pregnant) form means the following.

- They understand the teratogenic risks of isotretinoin.
- They agree to follow the contraception requirements of the iPLEDGE Program before, during, and for 1 month after their treatment with isotretinoin.

Prescriptions: System Requirements

Before a patient can obtain a prescription for isotretinoin at a registered pharmacy, the iPLEDGE Program system requires that the information below be entered into the system and the timing criteria for filling and dispensing a prescription be met. This is the information that the system will use to authorize filling a prescription and to provide the Risk Management Authorization (RMA) number and the **"Do Not Dispense To Patient After"** date.

All patients

Prescriber confirms that:

- The patient is registered with the iPLEDGE Program
- The patient was counseled on the iPLEDGE Program requirements

Females of reproductive potential

Prior to the patient obtaining each prescription, the prescriber must access the iPLEDGE Program system to:

- Confirm that the patient was counseled about isotretinoin and the iPLEDGE Program contraception requirements
- Enter the 2 forms of contraception that the patient is using
- Enter pregnancy result into the iPLEDGE Program system, within the 7-day prescription window, counting the date of blood draw or urine sample as DAY 1
- **The patient cannot answer her monthly questions and get a prescription filled until after these activities are completed by the prescriber.**

A positive pregnancy test prevents the prescription from being filled.

Patient must access the iPLEDGE Program system after the prescriber has entered the pregnancy test results to:

- Correctly answer the questions about the iPLEDGE Program and pregnancy prevention
- Enter the 2 forms of contraception she is using

The primary form of contraception reported by both the prescriber and the patient must match.

Timing criteria for the prescription to be obtained from the Pharmacy

- All patients must obtain their prescriptions as follows:
  - For male and female patients who cannot get pregnant, prescriptions must be obtained within the 30-day prescription window, counting the office visit as DAY 1
  - For female patients who can get pregnant, prescriptions must be obtained within the 7-day prescription window counting the day of the blood draw or urine sample as DAY 1
- Patients will not be able to obtain prescriptions after their prescription window has expired.

The iPLEDGE Program system will automatically provide the pharmacist with a "Do Not Dispense To Patient After" date, which is the end of the prescription window. The pharmacist cannot fill or dispense the patient's prescription after that date.

After The Last Dose

All patients should be reminded not to give blood for at least 1 month after their last dose.

Females of reproductive potential must have pregnancy tests:

- After their last dose, and
- 1 month after their last dose
- If this information is not entered, the patient will be classified as Lost to Follow Up, and both the prescriber and the patient will be contacted for more information.

It is important to stress the need for continued contraception during the 1 month after the last dose. Patients also should be reminded to enter their 2 forms of contraception.

Post Treatment iPLEDGE Program Requirements

When a patient will no longer be taking isotretinoin, action is required by the prescriber to record specifics of the end of therapy. Specifically the following information is required by the iPLEDGE Program:

- If known when issuing the prescription, the prescriber will indicate that a prescription will be the last one for this patient. This will remind the prescriber of the patient requirements for post-treatment activity
- The prescriber **must** discontinue the patient within the iPLEDGE Program in one of the following ways:
  - On the website, select "Manage Patients", select the patient being discontinued, and choose the button for "Discontinue Patient".
  - On the phone system, select the option to "Manage Active Patients", and then select the option to "Complete or Discontinue Patient Treatment".

Please see accompanying complete product information, including boxed
CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

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- When discontinuing a patient through either the website or the phone system, the prescriber must enter the Date of Last Dose, and the reason why this patient will no longer be taking isotretinoin. This reason will be selected from a list presented by the iPLEDGE Program system, including Completed Therapy, Pregnancy, or Other. On the website, explanatory comments can also be provided, and may be required by the iPLEDGE Program system.
  - If the reason for discontinuation is related to an Adverse Event, please be as specific as possible in the comments entered in the iPLEDGE Program system.
- For females of reproductive potential, **a final pregnancy test is required at the date of last dose, and 30 days after date of last dose**.

If this information is not provided, and a patient has no activity in the iPLEDGE Program system for specific periods of time, the patient will be classified as Lost to Follow Up. If this occurs, prescribers and patients will be contacted by the iPLEDGE Program.

IN THE EVENT OF PREGNANCY

Counseling A Pregnant Patient

If a pregnancy does occur during isotretinoin treatment, isotretinoin must be discontinued immediately. The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Reporting Pregnancy

The iPLEDGE Program Pregnancy Registry

The iPLEDGE Program Pregnancy Registry collects data on pregnancies that occur in female patients who become pregnant while taking isotretinoin or within 1 month of their last dose. Data from the registry are reported to the FDA and are used to assess the effectiveness of the iPLEDGE Program. The data are also used to evaluate further ways to reduce fetal exposure. Information gathered in the iPLEDGE Program Pregnancy Registry will be used for statistical purposes only and will be held in the strictest confidence.

The prescriber must report to the iPLEDGE Program Pregnancy Registry any pregnancy case that he/she becomes aware of while the female patient is on isotretinoin or 1 month after the last dose. Report a pregnancy by calling **1-866-495-0654**. Select the option to "Report a Pregnancy." All pregnancies should also be reported to the FDA via the MedWatch number: 1-800-FDA-1088

In female patients taking isotretinoin

1. Positive pregnancy test results should be entered in the iPLEDGE Program system. A Safety Surveillance Associate will call the prescriber.
2. A prescriber should call the iPLEDGE Program Call Center if he or she does not have a pregnancy test result but thinks the patient is pregnant.

In partners of males being treated with isotretinoin

If the prescriber becomes aware of a pregnancy in the partner of a male patient taking isotretinoin, the prescriber should report this pregnancy to the iPLEDGE Program Pregnancy Registry. The information will be forwarded to the manufacturer of the specific isotretinoin product for follow-up.

Males And Birth Defects

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.[3]

Isotretinoin also has not been shown to affect a male's ability to father children. Studies did not show effects on sperm count, how sperm look, or how well they swim and move. (For more information, see page 3.)

DELEGATES AND OFFICE STAFF

The iPLEDGE Program allows the prescriber to delegate patient management to other prescribers registered with the iPLEDGE Program (these are known as delegates) and to designate office staff to assist with data entry (these are known as designees).

Delegating To Another Prescriber

The prescriber must first add the name and required information for delegates into the iPLEDGE Program system. This function also allows the prescriber to define time frames for delegation and add or delete delegates.

To delegate to another prescriber

The prescriber:

1. Logs in to the web site, **www.ipledgeprogram.com**
2. Chooses "Manage Delegates/Designees" from the Prescriber home page
3. Chooses "Manage Delegates" from the Manage Delegates and Designees page
4. Enters the desired Delegate's iPLEDGE user ID, and the date, if any, when the delegate's role is to expire.
5. Chooses "Add" new delegate for first-time entry

Office Designees

The iPLEDGE Program provides a unique username and password to identified office staff to allow them to perform the following activities for the prescriber:

- Register patients and maintain the patient's information in the iPLEDGE Program
- Enter patient pregnancy results
- Confirm patient counseling
- Discontinue patients
- Manage delegates
- Check patient's program status

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The following functions are available only to a prescriber:

- Prescriber registration
- Prescriber activation—initial and renewal
- Serious Medical Reasons Exemption process

A prescriber may have one or more office staff designees. Designees may be associated with one or more prescribers.

- They need to register only once, regardless of the number of prescribers with whom they are associated.
- They may support all the registered prescribers in a multi-physician practice.
- They have rights for any patient delegated to an assigned prescriber.

Rights to perform the functions depend on the prescriber's rights and program status.

- If a prescriber is not activated in the iPLEDGE Program system, neither the prescriber nor the designated office staff can register a patient.

Designated office staff may access the automated system but must provide their own user ID and date of personal significance as identifiers.

The registered and activated prescriber is responsible for all information entered and activities performed in the iPLEDGE Program system by the office staff designee.

To designate office staff

The prescriber:

1. Logs in to the web site, **www.ipledgeprogram.com**
2. Chooses "Manage Delegates/Designees" from the Prescriber home page
3. Chooses "Register New Designee" from the Manage Delegates and Designees page
4. Fills in the required information on the registration online form
5. Selects "Save and Print" to save the new information and print the registration form

The office staff designee:

1. Signs and dates the completed form
2. Faxes or mails the completed form to the number or address provided

A username and password will be mailed to the designee upon completion of the registration process. The designee uses them:

- To log in to the automated system
- On the first log in, to reset password and choose a Date of Personal Significance as a system identifier

REFERENCES

1 Dai WS, Hsu MA, Itri LM Safety of pregnancy after discontinuation of isotretinoin *Arch Dermatol.* 1989;125:362-355

2 Mitchell, Allen A MD Isotretinoin Survey Allen A Mitchell, MD and Carla M Van Bennekom RN, MPH Slone Epidemiology Center at Boston University For presentation at FDA Advisory Committee Meeting: February 26-27, 2004

3 Centers for Disease Control and Prevention Birth defects: frequently asked questions Available at: http //www.cdc.gov/ncbddd/bd/faq1.htm#Whatisabirthdefect Accessed August 8, 2005

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

ACTIVATING DESIGNEE REGISTRATION

iPLEDGE registration must be activated in the iPLEDGE Program system before a designee can interact with the iPLEDGE Program. Activation must occur annually.

- The designee should review *The Guide To Best Practices For the iPLEDGE Program* and *The iPLEDGE Program Prescriber Contraception Counseling Guide* to understand the program. Activation requires the designee to attest to the following statements in the iPLEDGE Program system:
  - **Isotretinoin is teratogenic and must not be used by pregnant women.** The goals of the iPLEDGE program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. With these program goals in mind, iPLEDGE data is routinely analyzed to identify actions of non-compliance.

Information entered into the iPLEDGE system is considered part of the patient's medical record, and can be used to investigate suspected non-compliance. Verified non-compliance with regard to the iPLEDGE Program requirements can result in removal from the iPLEDGE Program.

Prescribers are responsible for all iPLEDGE activities performed by their Office Staff Designees. If an Office Staff Designee is found to be non-compliant with the iPLEDGE Program, resulting actions, including possible removal from the iPLEDGE Program, can include both the designee and the prescriber.

- **Verified Non-Compliance may be reported to the FDA.**

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For More Information About Isotretinoin

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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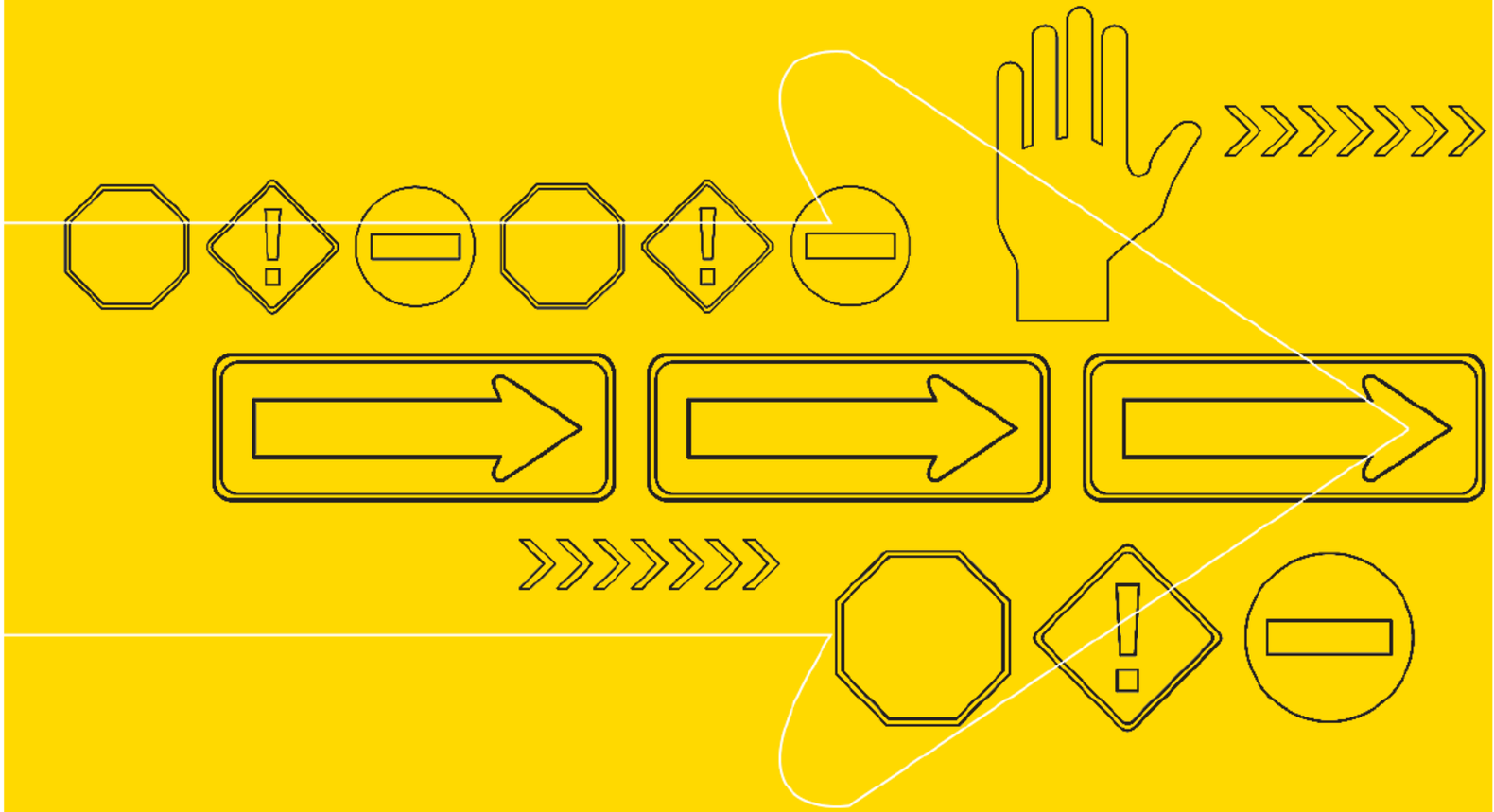

www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™
Committed to Pregnancy Prevention

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The iPLEDGE Program

Prescriber Contraception Counseling Guide

Helping patients prevent pregnancy

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INTRODUCTION

This *iPLEDGE Program Prescriber Contraception Counseling Guide* is intended to aid a prescriber who is not a gynecologist in counseling a female of reproductive potential who will be taking isotretinoin.

The patient must select and commit to using 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. Patients must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy.

It is strongly recommended that a patient use a primary form of contraception and is committed to using a second form as well, even if she says she will be abstinent for the entire required period. Isotretinoin is not recommended for sexually active females of reproductive potential whom you believe will not be able to maintain abstinence or will not use contraception, as the program requires.

The contraceptive that a patient selects can have a dramatic effect on her chance of becoming pregnant. A patient needs to select forms with low failure rates that she and/or her partner will use correctly each time they have intercourse. This *iPLEDGE Program Prescriber Contraception Counseling Guide* will help you enable the patient to select the 2 contraceptive forms that are consistent with the iPLEDGE Program guidelines *and* that she will use correctly and consistently.

Referral For Contraception Counseling

Before beginning treatment, the prescriber or patient may choose referral to a healthcare professional with expertise in pregnancy prevention. The makers of isotretinoin will reimburse 1 visit for contraception counseling. The patient educational kit contains the *iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the contraception requirements and the effective forms of contraception of the iPLEDGE Program for the birth control expert.

Contraception counseling is an important part of the patient choosing her two contraceptive forms. If practitioners are not comfortable providing this counseling, they are encouraged to take advantage of the opportunity to refer patients to a qualified counselor.

The referral form should be taken to the contraception counselor by the patient or sent in advance. The form instructs the counselor to fill in the appropriate information and return it to the prescriber with the patient's contraception choices to enter into the iPLEDGE Program system. The reverse side of the form has information for the counselor on the reimbursement process.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Counseling About Contraception

Please read this *iPLEDGE Program Prescriber Contraception Counseling Guide* completely before you begin your counseling session. The guide reviews the counseling goals and provides an overview of contraception choices from a pregnancy risk management context—necessary for female patients taking isotretinoin—information on obtaining a sexual and behavioral history (including additional guidance for interviewing an adolescent), and contraception reference materials.

Patients in the iPLEDGE Program receive *The iPLEDGE Program Birth Control Workbook*, which contains information on effective primary and secondary forms of contraception. It is not complete information on any of the forms, and the patient is encouraged to ask questions about specific forms or issues. The workbook has questions on such issues as medication adherence and lifestyle choices for the patient to think about in choosing contraception. Please review her responses with her.

COUNSELING GOALS

Ensure that the patient:

- Understands the risk of having a child with significant birth defects from exposure to isotretinoin.
- Understands the need for using 2 forms of contraception together consistently and correctly and knows when to contact her prescriber for emergency contraception (see page 27).
- Chooses the forms of contraception that will work best for her, that will provide her with the lowest practical failure rate, and that she and her partner will actually use. Adherence impacts the failure rate of hormonal combination oral contraceptives more strongly than other primary forms. (Please see "Hormonal Combination Oral Contraceptives As A Primary Form" on page 5.)
- Commits fully to not becoming pregnant and to using 2 forms of contraception simultaneously, consistently, and correctly. In previous isotretinoin risk management programs, patients understood the need for 2 forms of contraception; however, they did not comply, despite adequate information about the risk to the fetus. If, after counseling, the patient recognizes she will not be able to commit fully, encourage her to not take isotretinoin or do not prescribe.
- Is able and willing to maintain abstinence, if that is her choice after counseling. If a patient who has ever been sexually active chooses abstinence, and you believe that she will not be able to maintain abstinence and will not use contraception, encourage her to not take isotretinoin.

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Counseling younger teens

For younger teens, it is important to stress the following aspects of contraception for the iPLEDGE Program during counseling:

- The birth control forms that are effective as primary and secondary forms.
- Why it is important to use 2 forms of birth control. Younger teens may need more emphasis on this point to fully understand it and comply.
- The role of emergency contraception. Young teens may need more explanation from you about the need to take immediate action if they had unprotected sex. If she is under 18 years old, she may require a prescription or other assistance from a healthcare provider in order to use emergency contraception.

CONTRACEPTION REQUIREMENTS

Using 2 Forms Of Contraception Provides More Protection

Use of 2 forms of contraception simultaneously substantially reduces the chances that a female will become pregnant over the risk of pregnancy with either form alone.

In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin.[1] Because of this possibility, and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE Program requires the additional protection of a second form of contraception. The iPLEDGE Program requires the use of one "Primary Form" of contraception (Table 1) plus one "Secondary Form" of contraception (Table 2). Alternatively, the patient may select two primary forms of contraception.

Selecting An Effective Primary Form Of Contraception

Table 1 lists, by typical use failure rate, the primary forms of contraception acceptable in the iPLEDGE Program.

Table 1: Primary Forms of Contraception by Typical Use Failure Rate

	Percentage of Females Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Method	**Perfect Use**	**Typical Use**
Implantable Hormones	0.05%	0.05%
Partner's Vasectomy	0.10%	0.15%
Hormonal IUD (LNg 20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A)[b]	0.60%	0.80%
Hormonal Injectable (single)	0.20%	6.00%
Hormonal Transdermal Patch	0.30%	9.00%
Hormonal Vaginal Ring	0.30%	9.00%
Hormonal Combination Oral Contraceptives[b]	0.30%	9.00%

a. Adapted from Trussell J. Contraceptive failure in the United States. Contraception. 2011;83:397–404. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/. Accessed September 9, 2014.

b. The IUD Progesterone T and progestin-only "mini-pills" are not acceptable for the iPLEDGE program. (See "Unacceptable Forms Of Contraception" on page 7.)

The single most important decision in contraception for the iPLEDGE Program is selecting a primary form with a very low failure rate that the patient can and will use as perfectly as possible. Other important factors to consider in selecting a primary form include side effects, contraindications, and willingness and ability to use perfectly. (Perfect use is defined as the use of the form correctly and consistently covering every act of intercourse. Typical use reflects the practices of the average user.) All of these factors influence compliance and the chance of unwanted pregnancy.

Hormonal Combination Oral Contraceptives As A Primary Form

If the patient is currently taking or planning to take oral contraceptives, review that section in *The iPLEDGE Program Birth Control Workbook* with her. Her answers to questions on consistency and medication adherence will provide insight into potential issues with iPLEDGE Program adherence.

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Other contraception not requiring daily activity may be a better choice for a patient who is not likely to take oral contraceptives perfectly. For example, if such a patient chooses an IUD, she reduces her chances of becoming pregnant by up to approximately 90%.[1] It is critical that such a patient choose a form other than oral contraceptive agents.

Selecting An Effective Secondary Form Of Contraception

Table 2 lists the acceptable secondary forms of contraception in the iPLEDGE Program. There are 2 forms of secondary contraception: barrier and other. Barrier forms include the diaphragm and the cervical cap (both of which are always used with spermicide) and the male latex condom (which can be used with or without spermicide). The other form is the vaginal sponge, which contains spermicide.

Table 2: Secondary Forms of Contraception Listed by Typical Use Failure Rate

	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	Perfect Use	Typical Use
Barrier Forms		
Male Latex Condom[b]	2%	18%
Diaphragm*	6%	12%
Cervical Cap*,[d]	9%	20%
Other Forms		
Vaginal Sponge[c]	9%	12%

a. Adapted from Trussell J. Contraceptive failure in the United States. Contraception. 2011;83:397–404. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/. Accessed September 9, 2014

b. Male Latex Condom failure rates are for use without spermicide. Female condoms are not acceptable for the iPLEDGE program (See "Unacceptable Forms Of Contraception"on page 7.)

c. Failure rate for nulliparous women. The rate is approximately double for parous women.

d. Adapted from Trussell J. Contraceptive failure in the United States. Contraception. 2011;83:397–404. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/. Accessed September 9, 2014

* Failure rates for Diaphragm and Cervical Cap are for forms including the use of spermicide.

The most important issue for a secondary form is whether it will be used each time the patient has intercourse (i.e., will it be in place when the first form fails).

Help the patient select a secondary form that she and/or her partner can fully commit to using correctly each time they have intercourse. If it is apparent that more than 1 of the forms would be equally suited, select the form with the lower or lowest perfect use failure rate, as this will reduce the overall likelihood of becoming pregnant.

Unacceptable Forms Of Contraception

The following forms of contraception are not acceptable for the iPLEDGE Program:

- Progesterone-only "mini-pills,"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix‡

Patients currently using these forms of contraception must switch to effective forms of contraception. They must use 2 effective forms together consistently and correctly for at least 30 days and have a negative pregnancy test before beginning isotretinoin.

Emergency Contraception

- Review this section in *The iPLEDGE Program Birth Control Workbook* with the patient. (Also, see page 27 in this *iPLEDGE Program Prescriber Contraception Counseling Guide.*) She should know when to call her prescriber for possible emergency contraception. She should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms she selected.
- Emergency contraception is available over the counter.

Abstinence

If a female of reproductive potential cannot commit completely to abstinence while taking isotretinoin, she must use 2 separate, effective forms of birth control at the same time. The only exceptions are if she has had a hysterectomy, or had both of her ovaries removed (bilateral oophorectomy), or if she has been medically confirmed as post-menopausal.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception. See page 26.

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REFERRING TO A GYNECOLOGIST

You may want to refer your patient to a gynecologist for:

- An examination prior to starting oral contraceptive agents or a hormonal transdermal patch
- Insertion of an IUD or hormonal vaginal ring
- Fitting a diaphragm or a cervical cap
- More detailed explanation of contraception options

You should also ask for gynecologic consultation under the following circumstances:

- Your patient's history is suggestive of polycystic ovary syndrome (Stein-Leventhal syndrome). In addition to acne she may have:
  - Excessive facial hair growth (common when acne is present)
  - Obesity
  - Amenorrhea (no menstrual period) or irregular, heavy bleeding
  - Anovulation
- Your patient has irregular menses, possibly related to pregnancy; an eating disorder; or endometriosis. It is important to weigh your patient. Patients with eating disorders may:
  - Not admit to the problem
  - Be very underweight
- There are indications of sexual abuse found during the physical examination or counseling session.
- There is history or symptoms of sexually transmitted infection.

OBTAINING A SEXUAL AND BEHAVIORAL HISTORY

There are several reasons to take a sexual and behavioral history. You need to know about sexual promiscuity, risk-taking behavior, reactions to previous contraceptive medication, and current contraceptive practices to assess whether your patient is appropriate for the iPLEDGE Program. This information may help you eliminate unsuitable patients or refer those whose contraceptive needs require gynecologic referral.

General Interview Information

Preparation

Insure that your patient feels safe and comfortable.

- This is important for an effective counseling session.
- Allow time for taking the history, answering questions, and decision-making.
- A private office is more conducive to counseling than an examination room. This may permit a more open and personal exchange.
- Interruptions by other staff members and telephone calls should be discouraged.

Use open-ended questions to encourage discussion.

- Your patient may be reluctant or embarrassed to answer questions about her sexual history.
- It may help to start asking about less sensitive material.

Being objective and nonjudgmental is important in building rapport. Make sure your patient understands your questions and the information you are giving her. Listen to her use of language and tailor your language to be sure she understands.

Sexual history questions

1. Does she menstruate? Does she menstruate regularly?
   - Most females (95%) have their menstrual period every 21 to 35 days and usually in a recurrent and regular pattern. A female whose menses vary by a week or more from month to month or vary in length or quantity of flow would qualify as irregular.
2. Has she had a hysterectomy or oophorectomy?
3. Is she still menstruating?
4. Is she postmenopausal?
5. Is she sexually active?
   - If not, is there any possibility of a sexual relationship developing?
6. If she is sexually active, are her partners men, women, or both?
7. Has she ever used contraception? Does she currently use contraception?
   - If yes, what form(s) and for how long?
   - Specifically question the use of unacceptable forms such as the progesterone-only mini-pills or female condom.
8. If she uses oral contraceptives, does she take them exactly as prescribed? If so, which brands?
9. Does she use a secondary form of contraception every time she has sex? If so, which forms?
10. How many sexual partners has she had in the past 6 months? How many sexual partners does she currently have?

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11. How long has she been with her current partner(s)? Is she monogamous?
12. Has she ever had a sexually transmitted infection? Has she ever been sexually abused?
13. Has she ever been pregnant? Does she have children?
14. Has she ever had an unintended pregnancy? What was the outcome?

Behavioral history questions

1. Does she engage in risk-taking behavior, such as using drugs or alcohol?
2. How is she doing in school/at work?
3. How is her relationship with her parents? With her siblings?
4. What is her cohabitational status? Is she married? Living with a partner?
5. Is she currently using any prescription or non-prescription medications, herbal supplements, or vitamins?

Additional Guidance For Interviewing An Adolescent*

This section offers guidance on how to approach an adolescent to obtain a sexual and behavioral history, taking into consideration concerns adolescents have about independence, parental oversight, and privacy.

Discuss confidentiality first

- Inform the patient that she has a private and privileged relationship with you.
- Identify restrictions for which you may need to breach confidentiality, such as reporting physical or sexual abuse to health authorities.
- Tell her that you will not talk with her parent or parents about something she has said without discussing it with her first.

Start gently when asking about personal history

- Start with non-threatening topics and gradually move to more sensitive issues.
- Explain that you ask all of your patients about sexual activity and tell her why this information is important.
- Consider using one of the following questions to initiate the discussion about the patient's sexual history.
  - Are you dating anyone?
  - Are you intimate with anyone?
  - Are you physically close with anyone?

* Adapted from: Sexual History Taking. American College of Obstetrics and Gynecology, Committee on Adolescent Health Care, ACOG Committee Opinion No. 300. October 2004:p3.

Identify risk behaviors

- Leave room for discussing casual sex partners (who, for example, may not be perceived as "boyfriends").
  - Did you choose to have sex?
  - Has anyone forced you to have sex?
- Establish the sex of partner or partners first. Do not assume heterosexual behavior.
- Ask about oral and anal sex, and describe what you mean by this, if necessary.
  - Anal intercourse may be used by some teenagers to preserve virginity and protect against pregnancy, so they may not be using their secondary forms.
- Ask about the number of partners, STIs (sexually transmitted infections) and pregnancy prevention methods used.
  - Specifically, ask what methods the patient is using.
  - Find out if they are using unacceptable forms of contraception such as the progesterone-only mini-pill, female condom, or withdrawal.

Keep the lines of communication open

- Encourage adolescents to discuss these issues with their parents. You can assist the adolescent in telling her parents about her sexual activity and her need to use 2 forms of contraception for the iPLEDGE Program.
- Congratulate the patient for showing ability to think about her sexual health and be responsible.

CONTRACEPTION REFERENCE MATERIAL

The following sections contain some pertinent details, advantages, and disadvantages of the **primary** and **secondary** forms of effective contraception. This is not complete product information. Please refer to individual product labeling for contraindications, warnings and precautions, instructions for use, adverse events, and other product-specific information.

The percentages that follow for perfect use and typical use of a contraceptive are percentages of females having an unintended pregnancy during the first year of use, expressed as "1 female in X years."[2] Perfect use is defined as the use of the form correctly and consistently covering every act of intercourse. Typical use reflects the practices of the average user.

Reference ID: 3956479

PRIMARY FORMS OF CONTRACEPTION

The effective primary forms of birth control fall into 3 categories:

- Combination Hormonal Contraceptives
- Single Hormonal Contraceptives
- Non-Hormonal Contraceptives

None of the primary forms protect against STIs (sexually transmitted infections) or HIV (AIDS).

Combination Hormonal Contraceptives

Combination hormonal contraceptives include combination oral contraceptives, the transdermal patch, the vaginal ring, and hormonal implants. They use estrogen and a progestin in combination to suppress ovulation. In general, these forms have similar contraindications and adverse event profiles.

Hormonal Combination Oral Contraceptives[3]

With perfect use, the failure rate for combination oral contraceptives is equal to that of the best currently available contraceptive measure. **With typical use, oral contraceptives have the highest failure rate of the effective primary forms (Table 1).** Do not prescribe combination oral contraceptives for patients whom you do not think will take them exactly as prescribed. Other primary forms that do not require daily action by the patients, such as an IUD, may be a better choice for reducing the likelihood of pregnancy.

Note: Progesterone-only contraceptives (mini-pill) are not acceptable for the iPLEDGE Program because they are not an effective form of birth control. If your patient is using them, she will have to choose another effective primary form of birth control.

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)
Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Mechanism of action

Suppression of ovulation

Contraindications

- Thrombophlebitis disorders, history of deep vein thrombosis (DVT), or thromboembolic disorder
- Cerebral vascular or coronary artery disease
- Migraine with focal aura
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Acute or chronic hepatocellular disease with abnormal liver function
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy
- Hypersensitivity to product
- Smoking and over the age of 35

Other warnings

- Female patients with significant hypertension should not be started on oral contraceptives.
- Female patients who have had major surgery with immobilization or any leg surgery should not be started on oral contraception.
- Cigarette smoking increases the risk of serious cardiovascular adverse events with oral contraceptives. Female patients who use oral contraceptives should be strongly advised not to smoke. This risk is increased for female patients over 35 and those who smoke more than 15 cigarettes a day.
- Increased risk of venous thromboembolism and stroke.

Instructions for use

Once daily for hormone pills for a specified time period, often followed by placebos for a specified number of days. The patient should take oral contraceptives exactly as prescribed.
Missed pill(s):

- Any missed pills: discontinue intercourse for the remainder of the cycle
- Missed more than 2 pills: instruct the patient to call as soon as she realizes that she has missed 2 or more pills; she should be evaluated for possible emergency contraception, depending on her sexual activity. The patient should be counseled not to have intercourse for the rest of the cycle.

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Advantages

- May decrease the risk of the following:
  - endometrial and ovarian cancer
  - functional ovarian cysts
  - pelvic inflammatory disease
  - benign breast disease
  - ectopic pregnancy
- May decrease the incidence of dysmenorrhea and acne

Disadvantages

- Combination oral contraceptives do not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Common adverse events include breakthrough bleeding, nausea and vomiting, and headaches
- Associated with an increased risk of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease
- Less effective with medications affecting hepatic metabolism such as anticonvulsants; may be less effective with the antibiotics rifampin and griseofulvin,* possible interaction with St. John's Wort
- Isotretinoin may make hormonal forms less effective
- If pills are skipped or missed, the risk of pregnancy is very high

Hormonal Transdermal Patch[4]

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)

Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Contraindications

See "Contraindications," page 13.

Instructions for use

One patch is used per week for 3 consecutive weeks, on the same day of the week. The fourth week is patch-free. Menses occurs at this time.

If the female patient is starting the patch for the first time, she should wait until the day she begins her menstrual period.

* Adapted from ACOG Practice Bulletin, Number 18, July 2000.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Slipped or missed patches:

- If the patch falls off or is partially detached for less than 24 hours, the patient can reapply in the same place. Otherwise, replace with a new patch immediately. Change patches on the original schedule.
- If the patch is detached for more than 1 day or the patient is not sure how long the patch was detached, she should start a new cycle with a new change day by applying a new patch. It will not be effective for contraception for the first week.
- The patient should be instructed not to have intercourse during this first week.

Advantages

- It is not necessary to remember to take a daily pill
- Many female patients have more regular, lighter, and shorter periods
- Fertility returns quickly when the patch is stopped

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Less effective in female patients over 198 pounds
- Not effective if it becomes loose or falls off for more than 24 hours or if the same patch is left on the skin for more than 1 week
- Has the same labeling for contraindications, warnings, and precautions as oral contraceptives
- Common side effects include breakthrough bleeding, nausea, headaches and breast tenderness.
- Isotretinoin, antibiotics, St. John's Wort, and certain anticonvulsants may make hormonal forms less effective
- Possible increased risk of blood clots

Hormonal Vaginal Ring[5,6]

Rate of unintended pregnancies

Perfect Use: 0.3% (1 female in approximately 333 will become pregnant)
Typical Use: 9.00% (1 female in approximately 11 will become pregnant)

Contraindications

See "Contraindications," page 13.

Reference ID: 3956479

Instructions for use

Patient inserts ring in the vagina, where it should remain for 3 weeks. She removes ring for 1 week to bring on menses. A new ring is used each month for continuous contraception.

Advantages

- It is not necessary to remember to take a daily pill
- It does not need to be fitted by a clinician
- Many female patients have more regular, lighter, and shorter periods
- Fertility returns quickly when the ring is stopped

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- The ring cannot be used with a diaphragm or cervical cap
- Some female patients may have trouble inserting the ring
- It has the same labeling for contraindications, warnings, and precautions as oral contraceptives
- Efficacy of the ring is lessened if:
  - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
  - It slips out of the vagina and is not replaced in 3 hours
  - It does not stay in the vagina for 3 weeks
  - It is left in the vagina for more than 3 weeks
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Single Hormone Contraceptives (Progestin-only)

Single hormone forms contain a progestin that can suppress ovulation, thicken cervical mucus, and produce endometrial atrophy. Accepted forms include single hormone injection, the hormonal IUD, and implantable hormones. **Note: oral contraceptives containing no estrogen (progestin-only "mini-pills" see page 7) are not an acceptable form of contraception during isotretinoin therapy.**

Single Hormone Injections[3]

Rate of unintended pregnancies

Perfect Use: 0.2% (1 female in approximately 500 will become pregnant)
Typical Use: 6.00% (1 female in approximately 17 will become pregnant)

Contraindications

Pregnancy, unexplained abnormal vaginal bleeding, breast cancer or significant liver problems

Instructions for use

Injection every 12 weeks (150 mg/1 cc IM)

Advantages

- It works for 12 weeks at a time
- There is no daily pill to take
- It is good for female patients who cannot take estrogen

Disadvantages

Black Box Warning: Prolonged use of this [drug] may result in significant loss of bone density, and loss is greater the longer the drug is administered. Bone density loss may not be completely reversible after discontinuation of the drug. A female should only use this [drug] as a long-term birth control form (for example, longer than 2 years) if other birth control forms are inadequate for her.

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It can cause irregular bleeding
- It requires healthcare professional visit for injection every 12 weeks
- If patient is planning to get pregnant *after* she finishes isotretinoin treatment, it may take up to 18 months for return of ovulation.
- Isotretinoin may make single hormonal forms less effective

Reference ID: 3956479

Hormonal Intrauterine Device (IUD)[3,7]

The hormonal IUD is indicated for contraception in female patients who have had at least 1 child, are in a monogamous relationship, and are at low risk for STIs (sexually transmitted infections).

Rate of unintended pregnancies

Perfect Use: 0.2% (1 female in 500 will become pregnant)
Typical Use: 0.2% (1 female in 500 will become pregnant)

Contraindications

- Pregnancy or suspicion of pregnancy
- Congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity
- Acute pelvic inflammatory disease (PID) or history of PID without subsequent intrauterine pregnancy
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical neoplasia or unresolved, abnormal Pap smear
- Carcinoma of the breast
- Genital bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis, lower genital tract infections
- Acute liver disease or liver tumor (benign or malignant)
- Female patient or her partner has multiple sexual partners
- Conditions associated with increased susceptibility to infections with microorganisms
- Genital actinomycosis
- Previously inserted IUD that has not been removed
- History of ectopic pregnancy or condition that would predispose to ectopic pregnancy

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Instructions for use

The IUD is inserted by a healthcare professional. The patient should check for IUD strings often in the first few months after insertion and after each period. If the patient cannot find the strings, the strings feel shorter or longer, she can feel the IUD itself, there are any signs of symptoms of PID, or she misses a period, instruct her to call her prescriber.

Advantages

- It can be used for long-term contraception (5 years) and is relatively quickly reversible (i.e., return to fertility).

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It requires insertion and removal by a healthcare professional
- Common adverse events include menstrual changes, lower abdominal pain and cramping, acne or other skin problems, back pain, breast tenderness, headache, mood changes, nausea
- Enlarged ovarian follicles have been diagnosed in about 12% of hormonal IUD users; most disappear spontaneously during 2 to 3 months of observation
- All types of IUDs may increase the risk of pelvic inflammatory disease (PID); side effects of all types of IUDs may include cramps and heavier and longer periods in the first few months after it is placed
- IUD may be expelled, often during menses
- Isotretinoin, antibiotics, St. John's Wort, and certain anticonvulsants may make hormonal forms less effective
- IUDs may cause menstrual changes or amenorrhea
- If a pregnancy occurs, it is more likely to result in an ectopic pregnancy

Implantable Hormones[3]

Description

Implantable hormones (etonogestrel implant) are a long acting (up to 3 years), reversible method of progestin only contraception. This form of contraception involves a sterile rod(s), the size of a matchstick, for subdermal insertion under the skin on the inner side of the upper arm during a minor in-office surgical procedure.

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Rate of Unintended pregnancies

Perfect Use: 0.05% (1 female in 2000 will become pregnant)
Typical Use: 0.05% (1 female in 2000 will become pregnant)

Contraindications

- Known or suspected pregnancy
- Current or past history of thrombosis or thrombotic disorders
- Hepatic tumors (benign or malignant), active liver disease
- Undiagnosed abnormal genital bleeding
- Known or suspected carcinoma of the breast or personal history of breast cancer
- Hypersensitivity to any of the components of the implant

Advantages

- Effective birth control for up to 3 years
- It is not necessary to remember to take a daily pill
- Fertility may return quickly when Implant is removed
- Can be used in patients who cannot take estrogen

Disadvantages

- Implant does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- May cause irregular and unpredictable bleeding or amenorrhea.
- Other side effects can include headache, acne, dysmenorrhea and emotional lability
- Associated with an increased risk of myocardial infarction, thromboembolism, stroke, hepatic neoplasia and gall bladder disease
- Complications of insertion can include: swelling, redness, pain, bruising, scarring, infection, paresthesias, bleeding, and hematoma
- Complications of removal include: a broken rod, scar tissue making removal more difficult
- Rarely, it can be difficult or impossible to remove which may result in a surgical procedure

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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- If pregnancy occurs, there is a higher chance of an ectopic pregnancy
- Ovarian cysts that usually disappear spontaneously
- Studies were not done in women who weighed more than 130% of their ideal body weight or patients who are chronically taking medication that induce liver enzymes, and it is possible that the implant may be less effective in women who are overweight
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective

If you use an implant, always verify its presence in the patient's arm immediately after insertion by palpation. Until you confirm proper insertion, your patient must use a non-hormonal contraceptive method and is not eligible to start isotretinoin.

Non-hormonal Contraceptives[3,8]

Accepted non-hormonal forms of contraception include the Cu T 380A IUD, tubal sterilization, and partner's vasectomy. These non-hormonal forms do not protect against STIs (sexually transmitted infections) or HIV.

Cu T 380A IUD

Perfect Use: 0.6% (1 female in approximately 166 will become pregnant)
Typical Use: 0.8% (1 female in 125 will become pregnant)

Description

Made of polyethylene covered with copper

Mechanism of action

Prevents fertilization by altering tubal and uterine transport of sperm

Contraindications

- Pregnancy or suspicion of pregnancy
- Abnormalities of the uterus resulting in distortion of the uterine cavity
- Acute pelvic inflammatory disease (PID) or a history of PID
- Postpartum endometritis or infected abortion in the past 3 months
- Known or suspected uterine or cervical malignancy, including unresolved, abnormal Pap smear
- Genital bleeding of unknown etiology

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- Untreated acute cervicitis or vaginitis, including bacterial vaginosis, until infection is controlled
- Diagnosed Wilson's disease
- Known allergy to copper
- Female patient or her partner has multiple sexual partners
- Genital actinomycosis
- A previously inserted IUD that has not been removed

Instructions for use

Patient should check for IUD strings often in first few months after insertion and after each period. If patient cannot find the strings, the strings feel shorter or longer, she can feel the IUD itself, there are any signs of symptoms of PID, or she misses a period, she should call her prescriber.

Advantages

- Female patients who cannot take hormones can use it
- It can be used for long-term contraception (10 years) and is relatively quickly reversible (i.e., return to fertility)

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- It requires insertion and removal by a healthcare professional
- It should be used in female patients who are not at risk for STIs (sexually transmitted infections)
- All types of IUDs may increase the risk of pelvic inflammatory disease (PID)
- Side effects of all types of IUDs may include cramps, and heavy, longer periods
- The IUD may be expelled, often during menses

Sterilization[3]

Female sterilization may be accomplished using a variety of techniques. They are all considered to be very effective, virtually permanent methods of pregnancy prevention and, with the exception of hysteroscopic tubal sterilization, are immediately effective. For purposes of the iPLEDGE Program, a patient should not be permitted to consider her hysteroscopic tubal sterilization as an accepted method of contraception unless she has had a confirmatory hysterosalpingogram (HSG) or other confirmation.

A partner's vasectomy involves the mechanical blocking of the vasa deferentia in males. This is an effective primary form of contraception which prevents fertilization by keeping sperm from entering the seminal fluid. Males should have semen analysis after 15 to 20 ejaculations to be sure semen is free from sperm. If the patient has more than 1 partner, each partner must be sterilized for male sterilization to be effective as the patient's only primary form. If the patient uses male sterilization as a primary form, she should be encouraged to choose another primary form as a second form.

Rates of unintended pregnancies

Tubal sterilization

Perfect Use: 0.5% (1 female in 200 will become pregnant)
Typical Use: 0.5% (1 female in 200 will become pregnant)

Partner's vasectomy

Perfect Use: 0.1% (1 female in 1,000 will become pregnant)
Typical Use: 0.15% (1 female in approximately 666 will become pregnant)

Advantages (for tubal sterilization)

- Very effective, virtually permanent means of contraception

Disadvantages (for tubal sterilization)

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Difficult to reverse
- Requires surgery
- If a pregnancy does occur, there is an increased risk of an ectopic pregnancy

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Advantages (for partner's vasectomy)

- Very effective, virtually permanent means of contraception

Disadvantages (for partner's vasectomy)

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Low success rate in reversing
- Requires surgery
- Not effective right away

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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SECONDARY FORMS OF CONTRACEPTION

Most of the secondary forms are barrier contraceptives that prevent sperm from entering the vagina (condom) or cervix (diaphragm and cervical cap). Barrier forms include the diaphragm and the cervical cap, both of which must be used with spermicide. The male latex condom can be used with or without spermicide. The vaginal sponge is a delivery system for spermicide and has spermicide embedded in it. Female condoms are not acceptable for the iPLEDGE Program.

Diaphragms and cervical caps are barrier contraceptives that are considered moderately effective when used in combination with a spermicide. The male latex condom is a barrier contraceptive that is considered moderately effective when used with or without spermicide. The vaginal sponge is also considered moderately effective. The most important issue is whether the secondary form will be used each time the patient has intercourse. If the patient selects a secondary form as the second form of contraception, she must understand how it is used and be fully committed to using it each time she has intercourse.

Female patients under 30 and female patients who have intercourse 3 or more times per week may have a higher failure rate with vaginal secondary forms.

Note: The female condom, a thin, flexible plastic tube that covers the cervical os, is not an acceptable secondary form for the iPLEDGE Program.

Male Latex Condom Used With or Without Spermicide[3]

If the patient does not feel she can convince her partner(s) to use a latex condom (with or without spermicide) each time they have intercourse, she would need to select another secondary form where she has the control or select a second primary form.

Rate of unintended pregnancies

Perfect Use: 2% when used without spermicide (1 female in 50 will become pregnant)
Typical Use: 18% when used without spermicide (1 female in 6 will become pregnant)

Male condom (Latex) may be used with or without spermicide

Instructions for use

Unrolled onto erect penis before there is any contact with female genitals; use only water-based lubricants with latex condoms

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Advantages

- Protects against STIs (sexually transmitted infections) and HIV (AIDS)
- Easy to buy, no doctor appointment needed, no pelvic exam needed
- Easy to tell when it breaks or slips, important for seeking emergency contraception
- May lower risk of cervical dysplasia and cancer[12]

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Disadvantages

- Condoms can break or slip during sex
- May decrease sensitivity and spontaneity, may have trouble maintaining erection
- Must remember to use every time

Diaphragm Used With Spermicide[3,9]

Rate of unintended pregnancies

Perfect Use: 6% when used with spermicide (1 female in approximately 17 will become pregnant)
Typical Use: 12% when used with spermicide (1 female in approximately 8 will become pregnant)

Description

Dome-shaped rubber cap with a flexible rim available in many sizes (50-95 mm diameter) and different styles

Warnings

- There is an association between Toxic Shock Syndrome (TSS) and diaphragm use.
- A diaphragm must be removed after 6 to 8 hours to decrease the risk of TSS.
- There may be increased risk of urinary tract infections, candidiasis, or bacterial vaginosis.
- A diaphragm may cause allergic reactions in females sensitive to latex or rubber.

Advantages

- Female patients can easily carry a diaphragm with them and have control of its use
- Immediately effective
- No hormones
- No interruption of sex play; can be inserted any time before intercourse and must stay in place for at least 6 to 8 hours after intercourse; a diaphragm should not be worn for more than 24 hours
- May lower risk of cervical dysplasia and cancer
- Can be used during a menstrual period

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Requires a prescription, pelvic examination, and periodic refitting; lasts about 1 to 2 years

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- Some female patients find it hard to insert
- Spermicide must be inserted in the vagina if there is repeated intercourse
- Can get pushed out of place during sex
- Must be checked for holes after sex and cleaned after use

Cervical Cap Used With Spermicide[3,10]

Rate of unintended pregnancies in nulliparous females

Perfect Use: 9% when used with spermicide (1 female in approximately 11 will become pregnant)

Typical Use: 20% when used with spermicide (1 female in 5 will become pregnant)

The failure rate is double in parous females.

Description

Deep rubber cap with firm rim and a groove inside the rim that fits snugly around the cervix

Advantages

- Same as diaphragm
- No need to add more spermicide if female patient has repeated intercourse
- Continuous protection for 48 hours

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Some female patients find it harder to insert than a diaphragm
- It cannot be used during a menstrual period
- Patient needs a prescription and a pelvic examination to fit a cervical cap; a cap lasts about 1 year.
- Must be checked for holes and tears after sex and cleaned after use
- Less effective with multiparous females

Vaginal Sponge (Contains Spermicide)[3,11]

Rate of unintended pregnancies in nulliparous females:

Perfect Use: 9% (product contains spermicide) (1 female in approximately 11 will become pregnant)

Typical Use: 12% (product contains spermicide) (1 female in approximately 8 will become pregnant)

The failure rate is double in parous females.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Description

Soft, disposable, non-abrasive polyurethane foam that is a delivery system for 1 gram of the spermicide, Nonoxynol-9

Advantages

- Female patients can easily carry a vaginal sponge with them and have control of its use
- Immediately effective
- No hormones
- No interruption of sex play; can be inserted any time before intercourse and is effective for up to 24 hours
- No need to put in more spermicide with repeated intercourse
- No special fitting, available over the counter
- Not associated with TSS

Disadvantages

- Does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- Less effective with multiparous females

EMERGENCY CONTRACEPTION[3]

Emergency contraception is indicated after sex without adequate protection:

- No contraception is used
- A secondary form slips or breaks
- Missed pill or injection
- Rape

Emergency contraception is provided as either emergency hormonal contraception or insertion of a Cu T 380A IUD.

Hormonal Emergency Contraception Pills (ECPs)

Emergency contraception is available without a prescription regardless of age. Patients must understand that the sooner ECPs are started, the more likely they are to be effective. Common side effects include nausea and vomiting. Consider prescribing medication to reduce these side effects.

Always consult complete Prescribing Information for any medications prescribed or currently being taken by your patient.

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Insertion of Cu T 380A IUD

The IUD is inserted within 5 days of unprotected sexual intercourse. IUD insertion for emergency contraception is not recommended for female patients who have not had a child or are at risk for sexually transmitted infections. These include female patients with more than 1 sex partner or whose partners have more than 1 partner, female patients with new partners, and female patients who have been raped.

The names and phone numbers of emergency contraception prescribers in your area can be obtained by calling toll free: 1-888-NOT-2-LATE (1-888-668-2528).

REPORTING A PREGNANCY

The iPLEDGE Program Pregnancy Registry

The iPLEDGE Program Pregnancy Registry collects data on pregnancies that occur in female patients who become pregnant while taking isotretinoin or within 30 days of their last dose. Data from the registry are reported to the FDA and are used to assess the effectiveness of the iPLEDGE Program. The data are also used to evaluate further ways to reduce fetal exposure. Information gathered in the iPLEDGE Program Pregnancy Registry will be used for statistical purposes only and will be held in the strictest confidence.

The prescriber must report to the iPLEDGE Program Pregnancy Registry any pregnancy case that he/she becomes aware of while the female patient is on isotretinoin or 1 month after the last dose. Report a pregnancy by calling **1-866-495-0654**. Select the option to **"Report a Pregnancy."** All pregnancies should also be reported to the FDA via the MedWatch number: 1-800-FDA-1088.

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NOTES:

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For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call **1-866-495-0654**.

Confidential birth control information can be obtained via the iPLEDGE automated phone line 24 hours a day, 7 days a week at **1-866-495-0654**. The subjects include:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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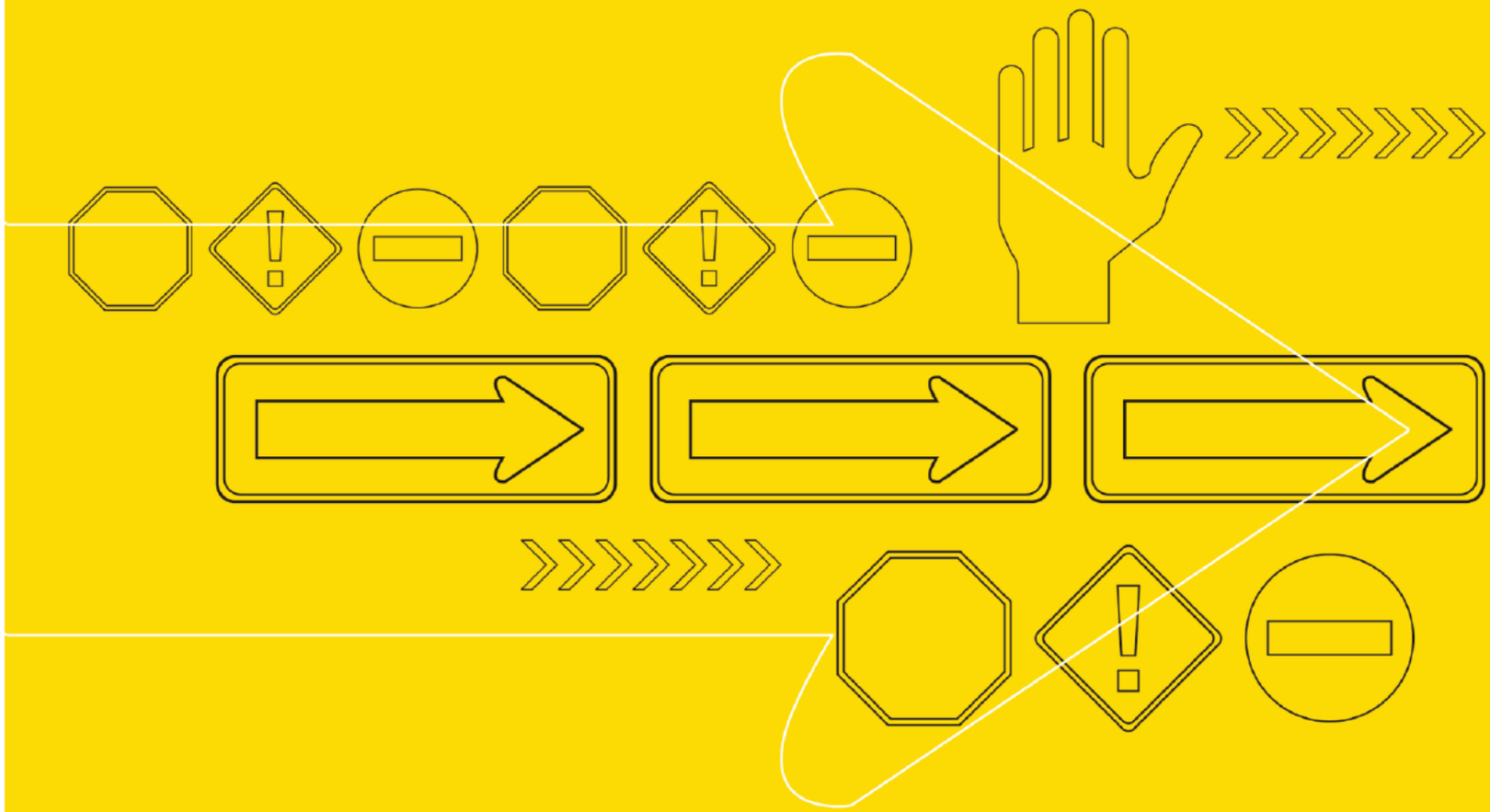

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Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

Committed to Pregnancy Prevention

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Recognizing Psychiatric Disorders In Adolescents And Young Adults

A Guide For Prescribers Of Isotretinoin

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

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Recognizing Psychiatric Disorders In Adolescents And Young Adults: A Guide For Prescribers Of Isotretinoin

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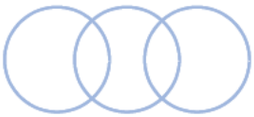

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see **PRECAUTIONS**).

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Warnings

Psychiatric Disorders: Isotretinoin may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. No mechanism of action has been established for these events (see ADVERSE REACTIONS: Psychiatric). Prescribers should read the brochure, *Recognizing Psychiatric Disorders In Adolescents And Young Adults: A Guide For Prescribers Of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of isotretinoin therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary. Signs and symptoms of depression, as described in the brochure *Recognizing Psychiatric Disorders In Adolescents And Young Adults*, include sad mood, hopelessness, feelings of guilt, worthlessness or helplessness, loss of pleasure or interest in activities, fatigue, difficulty concentrating, change in sleep pattern, change in weight or appetite, suicidal thoughts or attempts, restlessness, irritability, acting on dangerous impulses, and persistent physical symptoms unresponsive to treatment. Patients should stop isotretinoin and the patient or a family member should promptly contact their prescriber if the patient develops depression, mood disturbance, psychosis, or aggression, without waiting until the next visit. Discontinuation of isotretinoin therapy may be insufficient; further evaluation may be necessary. While such monitoring may be helpful, it may not detect all patients at risk. Patients may report mental health problems or family history of psychiatric disorders. These reports should be discussed with the patient and/or the patient's family. A referral to a mental health professional may be necessary. The physician should consider whether isotretinoin therapy is appropriate in this setting; for some patients the risks may outweigh the benefits of isotretinoin therapy.

Pseudotumor Cerebri: Isotretinoin use has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided. Early signs and symptoms of pseudotumor cerebri include papilledema, headache, nausea and vomiting, and visual disturbances. Patients with these symptoms should be screened for papilledema and, if present, they should be told to discontinue isotretinoin immediately and be referred to a neurologist for further diagnosis and care (see ADVERSE REACTIONS: Neurological).

Adverse Reactions

Neurological: pseudotumor cerebri (see WARNINGS: Pseudotumor Cerebri), dizziness, drowsiness, headache, insomnia, lethargy, malaise, nervousness, paresthesia, seizure, stroke, syncope, weakness

Psychiatric: suicidal ideation, suicide attempts, suicide, depression, psychosis, aggression, violent behaviors (see WARNINGS: Psychiatric Disorders), emotional instability

Of the patients reporting depression, some reported that the depression subsided with discontinuation of therapy and recurred with reinstitution of therapy.

Reporting adverse events

Specific information about adverse events that may occur during isotretinoin therapy may be reported to the individual makers of isotretinoin and/or to the Food and Drug Administration MedWatch Program at 1-800-FDA-1088 or via www.fda.gov/medwatch/report.htm.

The contact information for specific brands of isotretinoin can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Isotretinoin

Isotretinoin is a retinoid related to vitamin A. Patients should be advised against taking vitamin supplements containing vitamin A to avoid additive toxic effects.

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Introduction

Mental health problems are underdiagnosed and undertreated.[1] Dermatologists and other isotretinoin prescribers often see patients who are otherwise healthy, and they may be among the only professionals who have opportunities to evaluate patients' mental health. Healthcare providers who recognize the signs and symptoms of psychiatric illness and respond appropriately can improve, and perhaps even save, their patients' lives.

Isotretinoin may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Although causality has not been established for these reports, awareness of signs and symptoms may save your patient's life. This brochure provides an overview of depression. The goal of this brochure is to help you identify when a psychiatric consult is advisable.

You and your staff may feel uncomfortable evaluating your patients' mental health status. It is often difficult to distinguish clinical depression from other responses. It may also be difficult to decide whether erratic behavior may warrant psychiatric evaluation, especially if that behavior seems to be age-appropriate in a teenager. However, as with any specialize problem, you may identify patients who seem to need more than dermatologic care, and you may need to refer them to a specialist. Knowing when to make a referral for a patient who may be at psychiatric risk can make a major difference in the patient's life. In extreme cases, it can mean the difference between life and death.

Depression

Depression and suicidal tendencies are two important psychiatric conditions that may be observed in dermatology and family practice settings. This brochure provides an overview of depression because depression is the most commonly reported psychiatric adverse event in patients taking isotretinoin and is also a well established risk factor for suicidal behavior.

Depression is characterized by symptoms that include intense, persistent sadness; anxiety; loss of pleasure from usual activities; and loss of energy.[2] These feelings can be normal responses to a negative life event, but clinical depression is either not triggered by such an event or is disproportionate to the trigger.[3]

Depression can be episodic. According to the National Comorbidity Survey, 16.2% (between 32.6 and 35.1 million) of Americans will experience depression at some point during their lives, and 6.6% (between 13.1 and 14.2 million) are depressed in any given month.[4,5] Several epidemiological studies reported that up to 8.3% of adolescents in the United States suffer from depression.[6] Older adolescents experience more depressive symptoms than adults and comparable symptom persistence, suggesting that these adolescents may be at the highest risk for depression.[7]

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Depression can take several forms: three of the most common are dysthymia, major depression, and bipolar disorder.[2] These three disorders are characterized by various combinations of the symptoms listed in Table 1. Not every patient exhibits all depressive symptoms. Some patients, especially adolescents, may display irritability instead of sadness.

TABLE 1. Symptoms of depression

- Persistent sad, anxious, or "empty" mood
- Feelings of hopelessness, pessimism
- Feelings of guilt, worthlessness, helplessness
- Irritability, restlessness
- Loss of interest in activities or hobbies once pleasurable including sex
- Fatigue or decreased energy being "slowed down"
- Difficulty concentrating, remembering details, and making decisions
- Insomnia, early-morning wakefulness, or excessive sleeping
- Overeating, or appetite loss
- Thoughts of suicide, suicide attempts
- Aches or pains, headaches, cramps, or digestive problems that do not ease even with treatment.

Table 1 modified from National Institutes of Health. "What is Depression?" Available at: http://www.nimh.nih.gov/health/publications/depression/index.shtml. Accessed September 8, 2014

Dysthymia has characteristics similar to those of major depression but is not as disabling. People with dysthymia often function adequately but not at previous wellness levels, and are at risk for episodes of major depression. In major depression, a combination of symptoms prevents the patient from working, studying, and/or engaging in normal activities.

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In bipolar disorder, the patient alternates between periods of depression (severe lows) and episodes of mania (severe highs).[2]

Symptoms of mania[2]

- Abnormal or excessive elation
- Unusual irritability
- Decreased need for sleep
- Grandiose notions
- Increased talking
- Racing thoughts
- Increased sexual desire
- Markedly increased energy
- Poor judgment
- Inappropriate social behavior

Causes of depression

The causes of depression are often multifactorial and may include:

- Genetic predisposition[2]
- Stress at home, work, or school[2]
- Loss of a parent or loved one[8]
- Alcohol or substance abuse[9]
- Breakup of a romantic relationship[10]
- Medications[11]

Suicide

Suicide accounts for more than 30,000 American deaths each year. It is the third leading cause of death (after accidents and homicide) among people aged 15 to 24, which makes it responsible for more deaths in this age group than any physical illness.[12–14] Of the total number of suicides among people ages 15 to 24 in 2001, 86% were male and 14% were female.[15, 16] Healthcare providers often miss the warning signs because patients may hide suicidal intent very successfully. In fact, 60% of people who commit suicide had seen a physician within 1 month of their deaths.[9] Suicidal tendencies rarely arise spontaneously; 93% of people who commit suicide suffer from depression, schizophrenia, and/or substance abuse.[17]

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Up to 60% of adolescents and young adults think about suicide at some point,[12] but fortunately these thoughts usually pass. Few people who have suicidal thoughts make the attempt, and most attempts at suicide are unsuccessful.[13] The following are some elements of a suicide risk assessment that can be used to determine the individual's risk level for suicide[18]:

- Ideation (thoughts of death or suicide)
- Suicidal intent
- Plan (specific time, place, and method)
- Means (e.g., a firearm in the house or a supply of drugs)

Women are twice as likely as men to attempt suicide, but men are four times more likely to be successful. Women usually use means from which they may be rescued, such as a drug overdose,[19] whereas men tend to use firearms or automobiles. Firearms are used in 55% of all completed suicides.[13]

Despite a patient's attempt to hide suicidal thoughts, he or she may send deliberate warning signals, some of which can be explicit.[2] Every mention or discussion of "killing myself" should be treated with utmost seriousness.

Evaluating And Referring Patients For Psychiatric Disorders

Although only 5% of the population is depressed at any given time,[20] the incidence has been found to be closer to 15% to 20% in primary care settings.[21] Given that 1 in 5 patients who come to your office may have some degree of depression, a few questions can identify patients who may be at risk.

It is important to find out whether a patient is under care or has ever been under care for an emotional problem or psychiatric disorder, particularly depression. Knowing a patient's current medications, for example, if he or she is taking antidepressants, can further identify those patients who may be at even greater risk than the general population.

Talking About Depression

Although it can be awkward to explain to a patient that he or she may have signs of depression (or any mental illness), the awkwardness can be minimized by reminding the patient that:

- Depression is very common
- It matches some of the symptoms the patient described
- It is treatable

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Assessments: Depression

While taking a history, the prescriber should suspect the likelihood of depression if the patient has symptoms such as[6]:

- Persistent sad or irritable mood
- Loss of interest in activities once enjoyed
- Significant change in appetite or body weight
- Difficulty sleeping or oversleeping
- Psychomotor agitation or retardation
- Loss of energy
- Feelings of worthlessness or inappropriate guilt
- Difficulty concentrating
- Recurrent thoughts of death or suicide

In children and young adolescents, other signs to look for include[6]:

- Frequent, vague, non-specific physical complaints such as headaches, muscle aches, stomach aches, or tiredness
- Frequent absences from school or poor performance in school
- Talk of or efforts to run away from home
- Outbursts of shouting, complaining, unexplained irritability, or crying
- Being bored
- Lack of interest in playing with friends
- Alcohol or substance abuse
- Social isolation, poor communication
- Fear of death
- Extreme sensitivity to rejection or failure
- Increased irritability, anger, or hostility
- Reckless behavior
- Difficulty with relationships

The prescriber should also discuss with the patient:

- Alcohol or substance abuse
- Chronic pain
- Real or perceived disfigurement

Studies indicate that acne is associated with symptoms such as social embarrassment, low self-esteem, and anxiety, but an association of acne with frank depressive disorders has not been established, nor has treatment of acne by itself been shown to ameliorate frank depressive disorders.[22-24]

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Assessments: Suicide

Psychiatric specialists have identified several factors for suicide risk. These include[19]:

- Presence or history of depression, bipolar disorder, or other psychiatric disorder
- Access to firearms in the home
- Family history of suicide or violence, including abuse
- Poor physical health, chronic illness, or chronic pain
- Alcohol or substance abuse
- Previous suicide attempt

It is important to note that depression itself is a major risk factor for suicidal behavior.[19] Thus, special attention is needed when prescribing drugs that may cause depression. An association with isotretinoin should be considered in patients with signs and symptoms of depression, even in the presence of other life stressors. Discontinuation of isotretinoin may be insufficient intervention and a formal psychiatric evaluation should be conducted. It is also important to note that signs and symptoms of depression are not included in all reported cases of suicidal behavior. It is not known if this means the signs were masked by the patient, unrecognized by observers, or if the suicidal tendency arose impulsively. It is important that patients taking isotretinoin be made aware of this so that they might recognize any such signs and symptoms. Patients (and parents, if the patient is a minor) should be instructed to stop isotretinoin and seek immediate medical help.

Talking with patients about suicide does not encourage or remind them that suicide is an option.[19]

Knowing When To Refer

You should refer the patient to a psychiatric specialist for further evaluation if any of the following apply:

- Risk factor(s) for suicide is (are) present
- The patient has, or may have, clinical depression or bipolar disorder, or if the prescriber believes that there may be a problem but cannot classify it
- The patient has expressed interest in, or spontaneously mentioned, suicide
- There is any question about the patient's safety

Summary

Prescribers who are alert to the warning signs of psychiatric disorders can guide patients to receive the help they need. Observing patients for signs of depression and suicidal ideation, and referring appropriate patients to a psychiatric specialist, need not be complicated. The benefits to patients can be immense, even life saving.

National Suicide Prevention Lifeline
1-800-273-8255
http://www.suicidepreventionlifeline.org/

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Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

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Be Aware Video Script

Opening Segment
"ISOTRETINOIN CANNOT BE TAKEN BY WOMEN WHO ARE PREGNANT, BECAUSE ISOTRETINOIN CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY.

In this video we will see what can happen to an unborn baby if the baby's mother takes isotretinoin.

A woman must not take isotretinoin at any time during pregnancy.

Storyboard P2
Isotretinoin is usually prescribed for males and females to treat the most severe form of acne called nodular acne. This type of acne cannot be cleared up by any other acne treatments, including antibiotic pills. Nodular acne has many red, swollen, tender lumps that form in the skin. These lumps are the size of a pencil eraser or larger and can result in permanent scars if not treated.

Because of serious side effects and birth defects, patients should use isotretinoin only if other treatments including antibiotic pills have not worked.

Storyboard P3
"FEMALE PATIENTS MUST NOT TAKE ISOTRETINOIN IF THEY ARE PREGNANT, PLAN TO BECOME PREGNANT OR BECOME PREGNANT DURING THERAPY. TO AVOID PREGNANCY, WOMEN MUST USE TWO FORMS OF EFFECTIVE CONTRACEPTION ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE TAKING ISOTRETINOIN, AND FOR ONE MONTH AFTER STOPPING ISOTRETINOIN UNLESS THEY ARE ABSOLUTELY ABSTINENT, NEVER HAVING SEX, OR HAVE HAD THEIR UTERUS OR WOMB REMOVED".

Storyboard P4
"ISOTRETINOIN CAPSULES BREAK DOWN IN THE BODY AND THE MEDICINE ENTERS INTO THE BLOODSTREAM

Storyboard P5
"AND THE BLOOD IS CARRIED INTO THE PLACENTA WHERE IT REACHES THE UNBORN FETUS.

The medicine can cause severe birth defects."

Storyboard P6
"It is highly possible that the unborn baby may die because the baby's mother took isotretinoin."

Storyboard P7
"If the fetus lives, as the fetus develops, several birth defects can begin to take place.

These birth defects may be caused by taking isotretinoin during pregnancy".

Storyboard P8
"One of these birth defects may be abnormal skull development". "Use of isotretinoin during pregnancy may cause an under development or over development of the skull".

Storyboard P9
"Development of the ears may also be affected". "The ears may not fully develop if isotretinoin is used during pregnancy. The outer ear may be deformed and the ear canal may be very small or absent entirely causing deformity".

Storyboard P10
"The eyes also may not develop fully".
"The eye socket may be very small or not develop at all causing facial deformity

Storyboard P11
"As face structure begins to form the fetus can have a flattening of the nose and a twisting of the mouth. These birth defects could happen from using isotretinoin during pregnancy".

Storyboard P12
"The baby may also be born with a separation of the roof of the mouth and sometimes the lips which is known as a cleft palate".

Storyboard P13
IN ADDITION TO THE VISIBLE DEFECTS, SEVERAL INTERNAL SERIOUS AND LIFE-THREATENING BIRTH DEFECTS MAY DEVELOP IN THE HEART AND IN THE ENTIRE HEART AND BLOOD FLOW SYSTEM.

One of these defects can include an abnormal heart that has the arteries and veins in the wrong position.

Storyboard P14
"The system that helps to fight infection may also be affected. One of the glands in this system - the thymus gland may not develop and the baby then would have trouble fighting infections." "In addition, another gland -the parathyroid gland may not develop. The parathyroid gland helps the baby to form bones by controlling the amount of calcium in the body.

Storyboard P15
Brain and nervous system defects including an abnormal brain may occur…" OR AN UNDERDEVELOPMENT OF THE BRAIN. IT HAS ALSO BEEN REPORTED THAT SOME CHILDREN HAVE LOW IQ SCORES".

Storyboard P17
In summary, taking isotretinoin during pregnancy can result in any or all of these birth defects:

The skull may over- or under- develop.

FACIAL DYSMORPHIA CAN OCCUR, CAUSING A FLATTENING OF THE NOSE AND DISTORTION OF FACIAL STRUCTURE.

Enlargement of the brain may occur.

Eye sockets may be very small or not develop at all.

The brain can also under-develop.

Ears may not fully develop.

The thymus gland may not develop, affecting an infant's ability to fight off disease.

Abnormalities in the heart and entire cardiac system can be life threatening.

A cleft palate may form.

Storyboard P18
UNLIKE THE BIRTH DEFECTS THAT ARE SEEN IN THE BABIES WHEN MOTHERS TAKE ISOTRETINOIN, THERE IS NO PATTERN OF BIRTH DEFECTS WHEN FATHERS TAKE ISOTRETINOIN.

"But men who take isotretinoin should be careful in other ways." Men might not realize that they should not donate blood during, and for a period of one month following, the end of their isotretinoin treatment".

Storyboard P19
"As discussed earlier, isotretinoin is carried through the bloodstream and a pregnant woman could, unknowingly accept a blood transfusion from a man or a woman who took isotretinoin. The blood and medicine could then pass into the placenta possibly harming an unborn baby".

Therefore, it is extremely important that both men and women taking isotretinoin do not donate blood during treatment and for a period of at least one month following the end of their isotretinoin treatment.

Storyboard P20
"Neither men nor women should *ever* share their isotretinoin with another woman..."

Storyboard P21
"...BECAUSE OF THE RISK THAT SHE MAY BE PREGNANT."

"No one should ever share any medicine with anyone else, because the medicine may harm the other person."

Black Box

YOU MUST NOT BECOME PREGNANT WHILE TAKING ISOTRETINOIN, OR FOR ONE MONTH AFTER YOU STOP TAKING ISOTRETINOIN.

Isotretinoin can cause severe birth defects in babies of women who take it while they are pregnant, even if they take isotretinoin for only a short time.

There is an extremely high risk that your baby will be deformed or will die if you are pregnant while taking isotretinoin. Taking isotretinoin also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for isotretinoin unless there is proof they have had two negative pregnancy tests. The first test must be done when your prescriber decides to prescribe isotretinoin. The second pregnancy test must be done during the first five days of the menstrual period right before starting isotretinoin therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for isotretinoin unless there is proof that they have had a negative pregnancy test.

WHILE YOU ARE TAKING ISOTRETINOIN, YOU **MUST** USE EFFECTIVE BIRTH CONTROL. **YOU MUST USE 2 SEPARATE, EFFECTIVE FORMS OF BIRTH CONTROL AT THE SAME TIME** FOR AT LEAST ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE YOU TAKE IT, AND FOR ONE MONTH AFTER YOU STOP TAKING IT. YOU CAN EITHER DISCUSS EFFECTIVE BIRTH CONTROL METHODS WITH YOUR PRESCRIBER OR GO FOR A FREE VISIT TO DISCUSS BIRTH CONTROL WITH ANOTHER PHYSICIAN OR FAMILY PLANNING EXPERT. YOUR PRESCRIBER CAN ARRANGE THIS FREE VISIT, WHICH WILL BE PAID FOR BY THE MANUFACTURER.

You must use two separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons that you would not need to use 2 separate methods of effective birth control:

☐1. You have had your womb removed by surgery– a hysterectomy or

☐2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during and for one month after isotretinoin treatment.

IF YOU HAVE SEX AT ANY TIME WITHOUT USING TWO FORMS OF EFFECTIVE BIRTH CONTROL, GET PREGNANT, OR MISS YOUR PERIOD, STOP USING ISOTRETINOIN AND CALL YOUR PRESCRIBER RIGHT AWAY.

Be Prepared, Be Protected

VIDEO SCRIPT

SCENE 1: ABSTINENCE

FEMALE 1: I thought I was abstinent. I guess I didn't know what abstinence really means. Now I do.

ANNOUNCER: It's important to know what abstinence means. Not having sex. Not once, twice, or ever. Just because you're not having sex now, doesn't mean you will have always be abstinent. You're only abstinent if you know you won't be tempted to have sex. And this becomes especially important when you are taking a drug that may cause birth defects to your unborn baby. Think about it: Are you *really* abstinent?

SCENE 2: UNPREPARED PREGNANCY

FEMALE 2: I can't believe I'm pregnant. It was just that one time. And I have been so careful. This can't be right.

ANNOUNCER: You have to be sure if you are having sex at any time you can't use any excuses. It doesn't matter if your periods are irregular, or if you think you can't get pregnant, or if you don't have sex frequently. And if you are on a medication that could be harmful to your unborn baby, you need to be especially and extremely careful. Once can be enough.

SCENE 3: WITHDRAWAL

FEMALE 3: We used withdrawal for a long time. But this time withdrawal just didn't work.

ANNOUNCER: Withdrawal is unreliable. Use effective birth control such as the contraceptive pill, diaphragm, condom, and if you are taking a medication that may cause birth defects to your unborn baby, use a combination of two. If you don't like the pill, you have other options such as long lasting contraceptive implants, injectables, and intrauterine devices—IUDs. Always practice safe birth control using reliable effective methods to avoid pregnancy.

SCENE 4: BEING UNPREPARED

FEMALE 4: This is so nice. (Thoughts of Female 4) *I didn't think this would happen. I mean at least not tonight. I'm so surprised and unprepared.*

ANNOUNCER: Be prepared and protected. Think about it before hand. You may have sex and you might get pregnant? Don't assume your partner will take responsibility. And if you are on a medication that may cause birth defects—think about your unborn baby. Be prepared and ready to use reliable effective forms of birth control.

SCENE 5: BIRTH CONTROL CAN FAIL

FEMALE 5: I can't believe this. There's a hole in my diaphragm. What if I get pregnant? What am I going to do?

ANNOUNCER: Your doctor or nurse can help you find out if you are really pregnant. If you are, they can give you advice. Always make sure your birth control is reliable and effective. And if you are on a drug that may cause birth defects, be sure you are doubly protected.

If you have any questions you should speak to your doctor or nurse. Carefully follow instructions provided by your prescriber, and consult with them if you have any questions about pregnancy, birth control, or your medical treatment.

[TYPE—NO VOICE]

Frame 1:

Complete Contraceptive Certainty = Be prepared Be protected

Frame 2:

You have just seen five scenarios with the most common reasons women have unwanted or ill-timed pregnancies.

Frame 3:

If you are not being completely abstinent, then

- Use birth control regularly
- Use the most effective types of birth control
- Be sure the method you choose is reliable
- Be prepared and be protected

Frame 4:

Brought to you as an educational service.

FDA REMS Submission

Patient Screens Inventory

iPLEDGE Program

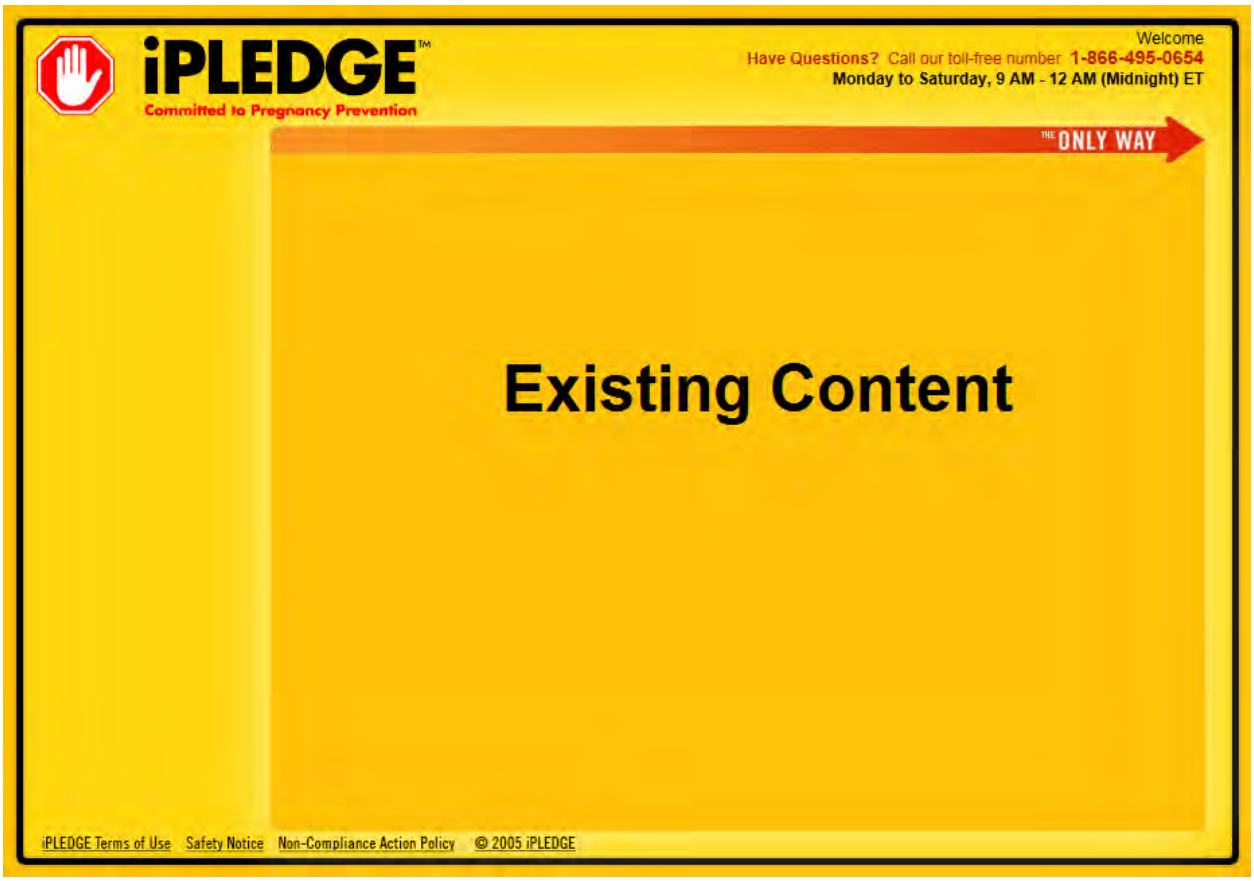
Revised: May 2016

Patient Screens Inventory:

- Common – Header and Footer
- Patient Registration – from Public Home Page
- Patient Home Page
- Comprehension Questions
- Contraception Information
- Patient Information
- About Isotretinoin
- About iPLEDGE
- Change Primary Prescriber
- Find a Participating Pharmacy
- Update My Information
- My Program Status
- FAQs/How To's
- Terms of Use
- Safety Notice

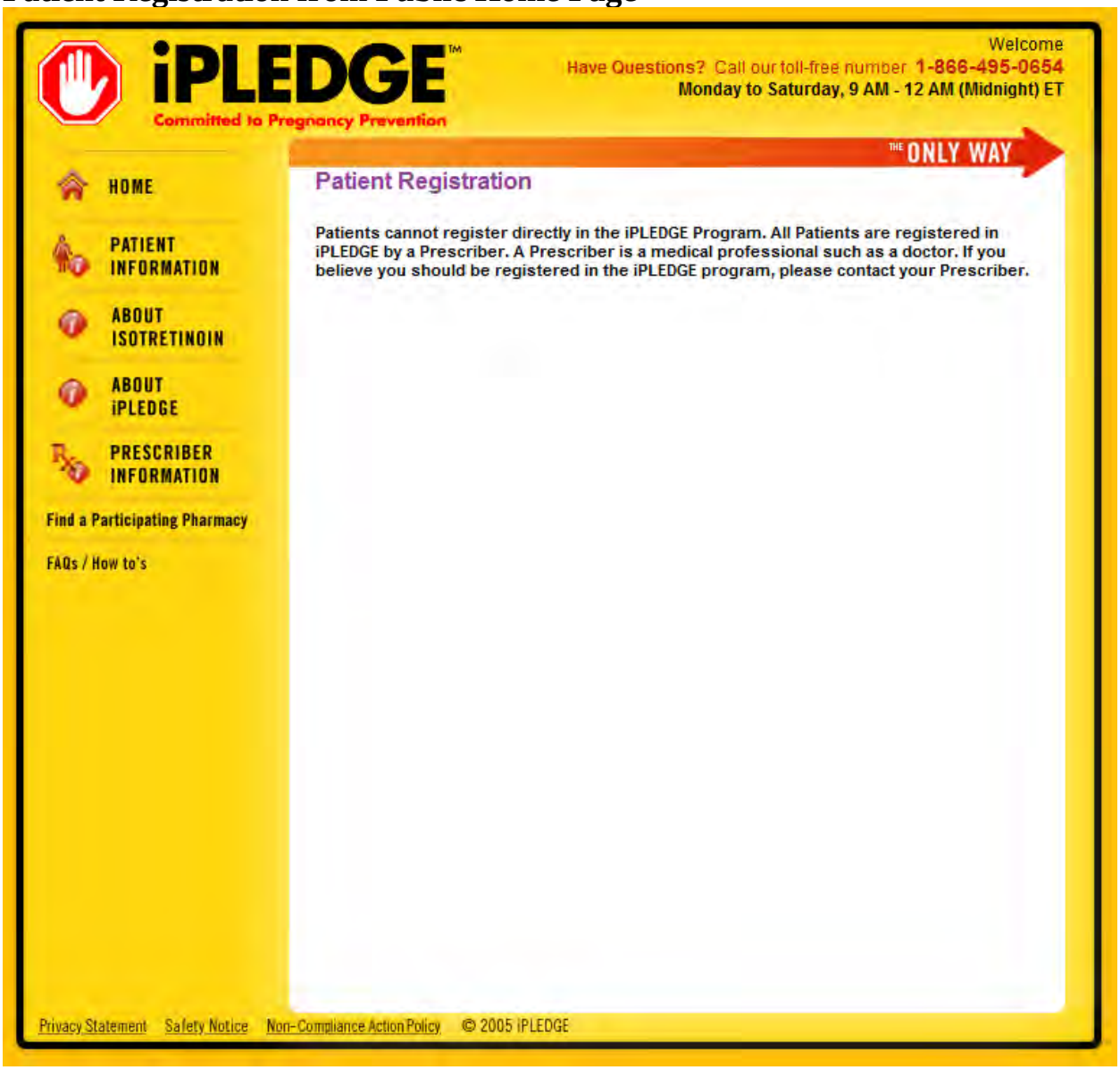
UBC
Reference ID: 3956479

Common – iPLEDGE Web page header/footer



UBC
Reference ID: 3956479

Patient Registration from Public Home Page



UBC
Reference ID: 3956479

Patient Home Page for Patient in Program Status "Required to Demonstrate Comprehension"

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Patient
Logout
Have Questions? Call our toll-free number 1-866-495-0654
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY

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SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Answer the Comprehension Questions

The iPLEDGE Program requires you to answer comprehension questions before every prescription. These questions will demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. You may not obtain your prescription until you have correctly answered the questions. You may use your iPLEDGE educational kit as a resource as you answer the questions.

Answer The Questions

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
To report a pregnancy, please call 1-866-495-0654 .

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Patient Home Page for Patient Not in Program Status "Required to Demonstrate Comprehension"

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SAFETY NOTICE

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Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Check My Program Status

My Program Status

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
To report a pregnancy, please call 1-866-495-0654 .

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Patient – Comprehension Questions- Did not fill Rx in previous window

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Answer Your Questions

Before You Get Started

iPLEDGE has no record of you filling a prescription in your prescription window from Oct 29, 2009 through Nov 4, 2009. Did you fill your prescription during this prescription window?

- Yes
- No

Note: Your answer will not restrict you from getting your prescription.

Submit

Reminder: Please be sure that your prescriptions are authorized in the iPLEDGE system by the Pharmacy. If the Pharmacy does not authorize the prescription in the iPLEDGE system, it could result in an unnecessary interruption in your treatment. Ask the Pharmacy if they have authorized this prescription, and look for the iPLEDGE sticker on your prescription bag. You may find a participating Pharmacy by using the Find a Pharmacy feature on the iPLEDGE website.

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Patient – Comprehension Questions

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Answer Your Questions

Please follow these two steps to demonstrate iPLEDGE Program comprehension.

Step 1: Birth Control Verification

Please enter the two forms of birth control that you are using. These must be the same two forms that you have told your Doctor that you are using. The answers you provide are used to determine what questions should be asked in step 2 below.

Additionally, the first month that you answer your questions, you will be asked a series of questions about information and counseling provided to you. There are no wrong answers to these questions. The answers are used to determine how often the iPLEDGE materials are shared with patients.

Step 2: Comprehension Questions

In order to get a prescription of isotretinoin, you must demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. You will be shown a series of questions and a list of multiple choice answers for each question. Only one of the answers will be the right answer for each question. If you choose the right answer, you will move on to the next question. If you choose the wrong answer, you will be shown the right answer for that question, and then you will move on to the next question.

When you have answered all the questions, you will be notified right away if you have passed or not. If you did not pass, you will be shown a list of the questions you got wrong and the right answers for those questions. You will also be shown where to find more information on these questions. You may attempt to answer the questions again after reviewing this information.

You will be allowed to pick up your prescription once you have correctly answered these questions.

Continue

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Patient – Comprehension Questions - Abstinence pop-up message

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary * Abstinence

Barrier/Primary *

More Information

Abstinence means that you will not have sex or sexual physical contact with any male 24 hours a day, 7 days a week. This can be hard to do. It is not a recommended way to prevent pregnancy for the iPLEDGE Program. One of the most common causes of unplanned pregnancy is failing to maintain abstinence (not being able to avoid sex).

You should really think about using birth control, even if you have never had sex – even if you are absolutely 100% certain you will not have any sexual contact with any male before, during and for 1 month after taking isotretinoin. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.

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Patient – Comprehension Questions – (after patient closes pop-up, and selects Abstinence as primary method) – Abstinence Confirmation

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Birth Control Verification

*denotes required field
Please select your contraception methods click the Submit button.

Primary * Abstinence
Barrier/Primary *

Important Information

- You have chosen abstinence and agree that you ***will not have sex*** or sexual contact with any male 24 hours a day, 7 days a week. If you cannot commit completely to not having sex (abstinence) while taking isotretinoin you MUST contact your prescriber before engaging in sexual activity.
- One of the most common reasons that women get pregnant is that they engage in sexual activity when they have planned to be abstinent.

I commit to abstinence | I cannot commit, I will contact my Prescriber

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If the patient selects abstinence, they will not be allowed to select a second method of birth control.

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Patient – Comprehension Questions - Patient Contraception and First Month Questions

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary * Birth Control Pills

Barrier/Primary * Male Latex Condom

Did your doctor or anyone in your doctor's office tell you that it is important not to become pregnant while taking isotretinoin? *

(•) Yes ( ) No

Did you receive the iPLEDGE Program Isotretinoin Educational Kit For Female Patients Who Can Get Pregnant? *

(•) Yes ( ) No

If yes, did you read

1. The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant? *
   (•) Yes ( ) No
2. The iPLEDGE Program Birth Control Workbook? *
   (•) Yes ( ) No

Did you watch the video, *"Be Prepared, Be Protected"* about birth control? *

(•) Yes ( ) No

Did you watch the video, *"Be Aware: The Risk of Pregnancy While on Isotretinoin"* about the effects of isotretinoin? *

(•) Yes ( ) No

Did your doctor or anyone in your doctor's office offer to refer you to another health care provider for birth control counseling? *

(•) Yes ( ) No

From whom did you receive birth control counseling? *

(•) My doctor
( ) Another health care provider
( ) I did not receive birth control counseling

Submit

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Patient – Comprehension Questions – Primary (First Time):

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary *

Barrier/Primary *

Birth Control Pills
IUD Progesterone T
Hormonal Skin Patch
Hormonal Vaginal Ring
Hormone Shot
Natural Family Planning
IUD
Under-the-skin Hormonal Implants
Tubal Sterilization
Progesterone-only Mini-pills
Partner's Vasectomy
Abstinence

Did your doctor or anyone in y ... ortant not to become pregnant while taking isotretin

Yes No

Did you receive the iPLEDGE P ... Female Patients Who Can Get Pregnant? *

Yes No

Did you watch the video, *"Be* ... ntrol? *

Yes No

Did you watch the video, *"Be Aware: The Risk of Pregnancy While on Isotretinoin"* about the effects of isotretinoin? *

Yes No

Did your doctor or anyone in your doctor's office offer to refer you to another health care provider for birth control counseling? *

Yes No

From whom did you receive birth control counseling? *

My doctor
Another health care provider
I did not receive birth control counseling

Submit

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Patient – Comprehension Questions – Barrier/Primary (First Time):

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary * Birth Control Pills

Barrier/Primary *

IUD Progesterone T
Hormonal Skin Patch
Hormonal Vaginal Ring
Hormone Shot
Natural Family Planning
IUD
Under-the-skin Hormonal Implants
Tubal Sterilization
Progesterone-only Mini-pills
Partner's Vasectomy
Fertility Awareness
Male Latex Condom
Female Condom
Diaphragm
Cervical Cap
Withdrawal
Vaginal Sponge
Cervical Shield

Did your doctor or anyone in y ortant not to become pregnant while taking isotretin
Yes No

Did you receive the iPLEDGE F Female Patients Who Can Get Pregnant? *
Yes No

Did you watch the video, *Be ntrol? *
Yes No

Did you watch the video, *Be n Isotretinoin* about the effects of isotretinoin? *
Yes No

Did your doctor or anyone in y another health care provider for birth control counseling? *
Yes No

From whom did you receive birth control counseling? *

My doctor
Another health care provider
I did not receive birth control counseling

Submit

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Patient – Comprehension Questions – Primary (Subsequent):

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary *

Barrier/Primary *

Submit

- Birth Control Pills
- IUD Progesterone T
- Hormonal Skin Patch
- Hormonal Vaginal Ring
- Hormone Shot
- Natural Family Planning
- IUD
- Under-the-skin Hormonal Implants
- Tubal Sterilization
- Progesterone-only Mini-pills
- Partner's Vasectomy
- Abstinence

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Patient – Comprehension Questions – Barrier/Primary (Subsequent):

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Birth Control Verification

** denotes required field*

Please select your contraception methods click the Submit button.

Primary * Birth Control Pills

Barrier/Primary *

- IUD Progesterone T
- Hormonal Skin Patch
- Hormonal Vaginal Ring
- Hormone Shot
- Natural Family Planning
- IUD
- Under-the-skin Hormonal Implants
- Tubal Sterilization
- Progesterone-only Mini-pills
- Partner's Vasectomy
- Fertility Awareness
- Male Latex Condom
- Female Condom
- Diaphragm
- Cervical Cap
- Withdrawal
- Vaginal Sponge
- Cervical Shield

Submit

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Comprehension Questions – Sample Question

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Comprehension Questions:

Program Steps

You are in your third month of treatment, in order to get your isotretinoin prescription, you must:

- Have a urine test for infection.
- Have a negative pregnancy test done in a laboratory, discuss birth control with your doctor and answer questions in the iPLEDGE system.

Submit Please select your answer to the question and click Submit.

Please do not use browser's Refresh, Back, or Forward buttons when answering the questions, or you may have to start again.

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Patient – Comprehension Question - Correct Answer - SAMPLE:

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Comprehension Questions:

Condoms

If you use a lubricant with a latex condom, it should be a water-based lubricant.

- (•) True
- ( ) False

Correct. You have selected the right answer.

Finish

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Patient – Comprehension Question - Incorrect Answer - SAMPLE:

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Comprehension Questions:

General Contraception Requirements

You have finished your last dose of isotretinoin. Your doctor has ordered a pregnancy test. For the next month, you:

- Continue to use 2 effective forms of birth contr
- Stop using your secondary form because you a
- Go for the pregnancy test at any time during the month.

Incorrect Answer. The correct answer is "Continue to use 2 effective forms of birth control together all the time."

Next →

Please do not use browser's Refresh, Back, or Forward buttons when answering the questions, or you may have to start again.

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Patient – Comprehension Test Results- SAMPLE:
Results: Failed

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Comprehension Questions Results

- Results: Failed to Demonstrate Comprehension
- You have answered the following questions incorrectly:

Important Note:
If this is your last month of treatment:

- Remember to continue using the two forms of acceptable birth control for 30 days after the last dosage.
- Get a pregnancy test after the last dosage *and* 30 days after the last dosage.

Click here to return to home page

Question: One goal of iPLEDGE is making sure pregnant women do not take isotretinoin
Answers

✓ True
✗ False

Explanation: The correct answer is 1. True. The iPLEDGE Program goal is preventing pregnancy and birth defects. iPLEDGE tries to make sure that a woman who begins treatment with isotretinoin is not pregnant and will not become pregnant while being treated and for 1 month after last dose.

Reference: The iPLEDGE Program Guide to Isotretinoin for Female Patients Who Can Get Pregnant, ABOUT Isotretinoin (see page 2).

Please review the Educational Materials before you answer the questions again.

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Patient – Comprehension Test Results- SAMPLE:
Results: Passed

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Comprehension Questions Results

- The questions are complete.
- You may obtain your prescription any time before 11:59 P.M. Eastern Time on 6/9/2015

Important Note:
If this is your last month of treatment:

- Remember to continue using the two forms of acceptable birth control for 30 days after the last dosage.
- Get a pregnancy test after the last dosage *and* 30 days after the last dosage.

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Contraception Information

- Isotretinoin and Birth Defects
- Sex, Pregnancy and Birth Control
- Different Methods of Birth Control
- Emergency Contraception
- Pregnancy and Pregnancy Testing

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Patient – Patient Information

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Patient Information

About Patient Information
Are you thinking about starting treatment with isotretinoin? You can learn more about isotretinoin and about the iPLEDGE program by reading the introductory information brochure and the medication guide available below.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.

Patient Information:

- The iPLEDGE Program Patient Introductory Brochure
- Mylan Amnesteem Medication Guide
- Teva Claravis Medication Guide
- Ranbaxy Sotret Medication Guide
- VersaPharm Myorisan Medication Guide
- Ranbaxy Absorica Medication Guide
- Dr. Reddy's Zenatane Medication Guide
- The iPLEDGE Program Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- The iPLEDGE Program Guide to Isotretinoin For Male Patients and Female Patients Who Cannot Get Pregnant
- The iPLEDGE Program Birth Control Workbook
- The iPLEDGE Program Contraception Referral Form and Contraception Counseling Guide
- Isotretinoin Contraception Referral Form
- Patient Flowchart

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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Patient - About Isotretinoin

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About Isotretinoin

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

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About iPLEDGE

The iPLEDGE Program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a **SINGLE** pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPLEDGE Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of childbearing potential. The iPLEDGE Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPLEDGE system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mIU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

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Change Primary Prescriber

If you change your Primary Prescriber, you will not be able to receive prescriptions from your current prescriber. Instead you will be receiving your future prescriptions from your new prescriber.

Please enter any or all search criteria and click the Search button

First Name	Last Name	Phone
iPLEDGE	Prescriber	
City	State	Zip Code
	PA	

Search

Found:

IPledge Prescriber
Blue Bell, PA,
215-234-2345

To transfer to this prescriber please click the Commit To Transfer button.
Please note: Your transfer will not be complete until your selected prescriber has accepted you as a patient.

Commit To Transfer

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Patient – Find a Participating Pharmacy

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Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button

Zip | City | State

Search

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Update My Information

Change Password

Change Date of Personal Significance

Update Contact Information

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Patient – Update My Information – Change Password

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Change Password

*denotes required field

Old Password *
New Password *
Confirm New Password *

Save Changes

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Patient – Update My Information – Change DOPS

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Change Date of Personal Significance

Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the Call Center.

** denotes required field*

Password: *

Date of Personal Significance: (MM/DD/YYYY) / / *

Confirm Date of Personal Significance: (MM/DD/YYYY) / / *

Save Changes

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Patient – Update My Information – Update Contact Information

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Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center.

** denotes required field*

First Name* iPledge
Last Name* Patient
Middle Initial O
Address* 920 Harvest Drive
City* Blue Bell
State* PA
Zip* 19422
Phone Number * 555-555-5555
Email * girija.doddapaneni@ubc.com
Preferred method of communication Email

Cancel | Save Changes

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Patient – My Program Status

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Patient Program Status

Prescriber: IPledge Prescriber (Change Primary Prescriber)
Program Status: Qualified to Receive Drug
Action: No patient action is required at this time.

Information: You may obtain your prescription at the pharmacy. You must obtain the prescription before 11:59 PM Eastern Time on the last day of your prescription window.

June 2015

Sun	Mon	Tue	Wed	Thu	Fri	Sat
31	1	2	3 If you haven't already, obtain your prescription More...	4 If you haven't already, obtain your prescription More...	5 If you haven't already, obtain your prescription More...	6 If you haven't already, obtain your prescription More...
7 If you haven't already, obtain your prescription More...	8 If you haven't already, obtain your prescription More...	9 If you haven't already, obtain your prescription More...	10 First day you may have your next pregnancy test More...	11	12	13

Key

- Today or future day for an active 7 day window
- A past day for a 7 day window
- A 7 day window that has expired without prescription fill
- Action may occur on this date or any date after

You may click on underlined text to perform the required action.

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Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PATIENT
C. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- How can I login using my telephone?

  To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system will ask you to indicate which type of user you are (prescriber, patient, pharmacy or designee) and then prompt you to enter your user ID followed by the # button. You may be presented with additional prompts to confirm your user id.

  For each character of your username, press the key on the touch pad that corresponds to the number or letter. For example, the 2 button on the phone is used to enter either the number 2 or the letters A, B and C. The # must be pressed after all characters have been entered.

  For example, if your username is 12345, type 12345# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 2512345#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.

B. PATIENT
C. PHARMACY
D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

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B. PATIENT
- How do I register with the iPLEDGE Program and receive my username and password?
- I either lost or forgot my password. How do I reset my password?
- How do I update my information?
- Why are males included in the iPLEDGE Program?
- Why can't I answer my comprehension questions?
- How can I find what is left to be completed before I am "Qualified to Receive Drug"?
- At what date and time does my prescription window close?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

C. PHARMACY
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HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- At what date and time does my prescription window close?

  Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may obtain your prescription. Patients will be provided with a message that states the ending date and time to obtain their prescription. This message has been updated to give patients the exact date and time when their prescription window will close. For example, the message will read:

  "You may obtain your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

  Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to obtain their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.

- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.

- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

C. PHARMACY
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HOW TO'S (click topics below for more information)

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Frequently Asked Questions (FAQ)

- How can I find what is left to be completed before I am "Qualified to Receive Drug"?

  The iPLEDGE system provides updated information on your status in the program. This includes information on your current or most recent prescription window, as well as links directly to the next steps required to meet the program requirements to become "Qualified to Receive Drug". You can access this information by choosing the "My Program Status" button from the menu options.

- At what date and time does my prescription window close?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

  Prior to filling the prescription, contact the pharmacy to ensure that they have enough product in stock to and dispense the prescription. The pharmacy must fill AND dispense the prescription within the prescription window. If the pharmacy cannot meet this deadline, the patient should go to another pharmacy. In most cases you will be able to re-start your window after your current prescription window expires. However, a potential lapse in treatment could result when a registered patient does not obtain the isotretinoin prescription within the prescription window.

C. PHARMACY
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HOW TO'S (click topics below for more information)

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Frequently Asked Questions (FAQ)

E. ALL USERS

- Does the iPLEDGE Program have a Privacy Statement?

  Yes. Everyone who wants to take the prescription medication isotretinoin is required to register and participate in the iPLEDGE Program. In order to help you fulfill the requirements of the program, iPLEDGE must obtain personal information from you. Protecting your privacy is very important to us. The complete iPLEDGE Privacy Statement can be found at the bottom of home page at http://www.ipledgeprogram.com/ by choosing the "Privacy Statement" feature.

- What happens if a patient loses his or her iPLEDGE ID card?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?
- At what date and time does my prescription window close?
- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?
- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- At what date and time does my prescription window close?

  Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may pick up your prescription. Patients will be provided with a message that states the ending date and time to pick up their prescription. This message has been updated to give patients the exact date and time when their window will close. For example, the message will read:

  "You may pick up your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

  Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to fill and pick up their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.

- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?

  Users can download the iPLEDGE materials from the website using Acrobat. The link to this free Acrobat download is available on any page that has materials available for download. The website has been updated to include additional documents for download and self-printing.

- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

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UBC
Reference ID: 3956479

Patient – iPLEDGE Terms of Use

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Committed to Pregnancy Prevention

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Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY

HOME
COMPREHENSION QUESTIONS
CONTRACEPTION INFORMATION
PATIENT INFORMATION
ABOUT ISOTRETINOIN
ABOUT iPLEDGE
Change Primary Prescriber
Find a Participating Pharmacy
Update My Information
My Program Status
FAQs / How to's

iPLEDGE Terms of Use

IPLEDGE TERMS OF USE

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.ipledgeprogram.com (the "**Site**"). The "**iPLEDGE Website**" is a Registered User-only account portal available through the Site which enables Registered Users to participate with a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"**Registered Users**" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "**Patients**" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program.

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Patient – Safety Notice

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- Update My Information
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Safety Notice

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

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STEPS TO REQUEST AN EXEMPTION FOR FEMALE PATIENTS WITH SERIOUS MEDICAL REASONS

Follow these steps to request an exemption from the iPLEDGE requirements for a female patient with serious medical reasons.

NOTE: The intent of this form is to request an exemption from the iPLEDGE requirements for a non-pregnant patient with serious medical reason(s) who is unable to obtain an isotretinoin prescription by completing the requirements in the iPLEDGE Program at this time. It is not intended to replace the requirements of the iPLEDGE Program.

1. Complete a new *Request for Exemption for Patients with Serious Medical Reasons* form. Print the completed form, sign and date.

2. **Fax the form (all pages) to 866-486-7001**.

Call 877-475-3345 if you need any assistance with the exemption request. If an agent is not immediately available, please leave contact information and the call will be returned. **Please note that this phone number must only be used for requesting exemptions for patients with serious medical reasons. No other iPLEDGE questions or issues will be handled through this number.**

NOTE: This form **MUST** be filled out and signed by the requesting prescriber. **All** required information (*) must be provided. Please FAX this completed form to **866-486-7001**.

*Prescriber ID	**"[click here and enter the prescriber's iPLEDGE ID]"**
*Prescriber Name	**"[click here and enter the prescriber's name]"**
*Patient ID	**"[click here and enter the patient's iPLEDGE ID]"**
*Patient Date of Birth	**"[click here and enter the patient's date of birth]"**
*Office Telephone Number	**"[click here and enter your telephone number]"**
* Office Fax Number	**"[click here and enter your fax number]"**

Forms received after 8PM Eastern Time will be processed on the next business day. Forms received after 8PM Eastern Time on a Friday will be processed the following Monday (or Tuesday, if Monday is a federal holiday).

iPLEDGE
P.O. Box 29094
Phoenix, AZ 85038
Exemption Phone Number: 1-877-475-3345
Exemption Fax Number: 1-866-486-7001
iPLEDGE Call Center: 1-866-495-0654

iPLEDGE™
Committed to Pregnancy Prevention

REQUEST FOR EXEMPTION FOR PATIENTS WITH SERIOUS MEDICAL REASONS

☐**Exemption Option 1 - Tanner Stage 1 or 2**

By selecting this option I attest that all of the following apply to this patient:

- Classified as Tanner Stage 1 (pre-pubertal female) or Stage 2 (female who has not yet experienced menarche or breast development)
- Not considered to be of reproductive potential
- Not currently pregnant
- I will evaluate this patient's reproductive status while receiving isotretinoin and I will notify the iPLEDGE Program within 10 business days of any change in the patient's reproductive status

☐**Exemption Option 2 - Expedite Start of Treatment**

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that she be exempt from the initial wait period
- Not currently pregnant
- Required to take monthly pregnancy tests
- Required to successfully complete monthly comprehension testing
- I understand that the patient will have 7 days to obtain her prescription from the date of the monthly pregnancy test specimen collection

☐**Exemption Option 3 – Cognitively and/or Physically Impaired**

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that she be exempt from the initial wait period and the monthly comprehension testing
- Not currently pregnant
- Required to take monthly pregnancy tests
- I understand that the patient will have 7 days to obtain her prescription from the date of the monthly pregnancy test specimen collection

Please make certain that you maintain medical documentation supporting the reason(s) for this exemption. The iPLEDGE program may require a copy.

- **The medical exemption process is governed by the iPLEDGE Non-Compliance Action Policy. Intentional misuse of the medical exemption process may result in Permanent Deactivation from the iPLEDGE program resulting in a permanent loss of isotretinoin prescribing privilege.**
- I attest that I am both qualified and have performed the necessary medical evaluation(s) to determine that the medical exemption is appropriate for this patient based on the iPLEDGE requirements.

*Signature _____

*Date of Request _____

PLEASE FAX COMPLETED COPY TO 866-486-7001

iPLEDGE
P.O. Box 29094
Phoenix, AZ 85038
1-866-495-0654

iPLEDGE – Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

REGISTERING AND MANAGING OFFICE STAFF DESIGNEES

As a registered prescriber, you may designate a member of your office staff to perform most patient activities for you in the iPLEDGE system. An Office Staff Designee must be registered in the iPLEDGE Program and receive a unique username and password. You may assign a member of your staff as your Office Staff Designee once the registration process has been completed. A registered and designated Office Staff Designee may perform most patient activities for you in the iPLEDGE system. A registered and designated Office Staff Designee may **NOT** confirm the serious medical reason(s) exemption process in the iPLEDGE system on your behalf, as the confirmation requires the digital signature of a registered prescriber.

The registered prescriber is responsible for all information entered and activities performed in the iPLEDGE system by the Office Staff Designee.

Registering An Office Staff Designee

Go to **www.ipledgeprogram.com** and log in by entering your username (DEA number or program-generated username) and password. You will be presented with the Prescriber home page. Select the **"Manage Delegates/Designees"** button. The Manage Delegates and Designees page will be displayed. Select the **"Register New Designee"** button. The Office Staff Designee Registration form will be presented. Have the Office Staff Designee follow the registration instructions on the form to complete the registration.

Managing Office Staff Designees

Go to **www.ipledgeprogram.com** and log in by entering your username (DEA number or program-generated username) and password. You will be presented with the Prescriber home page. Select the **"Manage Delegates/Designees"** button. The Manage Delegates and Designees page will be presented. Select the **"Manage Designees"** button to display the Manage Designees page. On the Manage Designees page, enter the Office Staff Designee's iPLEDGE username and select **"Add."**

It is important to note the following:

- Your Office Staff Designee's access to activities in the iPLEDGE system is dependent on your access to the system. Specifically, if you have not been activated in the system or if your activation has expired, your Office Staff Designee will not be able to perform activities in the iPLEDGE system.
- Although several prescribers may utilize the same Office Staff Designee, the Office Staff Designee only needs to register in the iPLEDGE Program once.

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Welcome TestPrescriber1 Gigamoto
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THE ONLY WAY

- HOME
- PRESCRIBER ACTIVATION
- REGISTER NEW PATIENT
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- MANAGE PATIENTS
- PRESCRIBER INFORMATION

Order Materials
Update My Information
Accept Patient
Manage Delegates/Designees
My Program Status
Find a Participating Pharmacy
FAQs / How to's
Action Required List

Register New Designee

Designees are office staff that are registered in the iPLEDGE program. To register the designee, enter the designee information and click the Save and Print button.

The registered prescriber is responsible for all information entered, and activities performed, in the iPLEDGE program by the office staff designee.

** denotes required field*

First Name* Last Name* MI

Address *

City* State* Zip*

Phone* Fax

Email

Preferred method of communication*

Save and print designee's registration

To complete your designee's registration, click the Save and Print button below, have the designee sign the form, then mail or fax the signed form to the address or fax number on the form.

Save and Print

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Register New Designee

Designees are office staff that are registered in the iPLEDGE program. To register the designee, enter the designee information and click the Save and Print button.

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** denotes required field*

First Name* Last Name* MI

Address *

City* State* Zip*

Phone* Fax

Email

Preferred method of communication*

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Save and Print

Designee Registration Print Page

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Designee Registration

Send To
iPLEDGE - Committed to Pregnancy Prevention
PO BOX 29094
PHOENIX AZ 85038-9978

Or Fax to
1-866-495-0660

Designee Number
W2041055

Your information
iPLEDGE V Designee
123 Test Drive Suite 200
Blue Bell, PA 18957
Phone 555-555-1212 Fax
Email ipledgeDES@test.com
Preferred communication method Email

Designee Signature _____ Date _____

Return to Home Page

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Welcome
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THE ONLY WAY

- HOME
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- PRESCRIBER INFORMATION

Find a Participating Pharmacy

FAQs / How to's

Prescriber Registration

Attention: This registration page is for licensed prescribers only. If you are a patient, you must be registered in iPLEDGE by your doctor.

Please provide your DEA number. This will be used as your Username to identify you in the program and for you to login to the iPLEDGE system using the phone or internet site. The DEA number provided must be your DEA number, not an institutional or shared DEA number. Please provide only one DEA number if you have more than one.

If you do not have a DEA number, check the box indicating that you would like the program to generate a Username to be used to identify you in the program. This program generated Username will be shipped to you in your prescriber educational kit.

DEA Number [ ] *or* ☐ Generate Username

Enter or confirm your information

** denotes required field*

First Name* | Last Name* | MI | Suffix (MD) | Specialty

Address*

City* | State* | Zip*

Phone* | Fax

Email

Preferred Method of Communication*

Select delegates

DEA Number or Username | Add | Delegate List

Expiration Date (MM/DD/YYYY) | Remove

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

Save and Print

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Prescriber Registration

Attention: This registration page is for licensed prescribers only. If you are a patient, you must be registered in iPLEDGE by your doctor.

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If you do not have a DEA number, check the box indicating that you would like the program to generate a Username to be used to identify you in the program. This program generated Username will be shipped to you in your prescriber educational kit.

DEA Number [ ] *or* ☐ Generate Username

Enter or confirm your information

** denotes required field*

First Name* | Last Name* | MI | Suffix (MD) | Specialty

Address*

City* | State* | Zip*

Phone* | Fax

Email

Preferred Method of Communication*

Select delegates

DEA Number or Username | Add | Delegate List

Expiration Date (MM/DD/YYYY) | Remove

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

Save and Print

Prescriber Registration Print Page

iPLEDGE™
Committed to Pregnancy Prevention

Have Questions? Call our toll-free number **1-866-495-0654**
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

Prescriber Registration

Send To
iPLEDGE - Committed to Pregnancy Prevention
PO BOX 29094
PHOENIX AZ 85038-9978

Or Fax to
1-866-495-0660

Username
2041023F

Your information
iPLEDGE V Prescriber MD Specialty OB/GYN
123 Test Drive Suite 200
Blue Bell, PA 18745-1245
Phone 125-555-1212 Fax 124-444-1212
Email ipledgePR@test.org
Preferred communication method Email

Your delegates
None Selected

Prescriber Signature _____ Date _____

Return to Home Page

Most Recent Modification: July 2016

The iPLEDGE Program

The Pharmacist Guide For the iPLEDGE Program

The resource to help the pharmacist understand and comply with the iPLEDGE Program for isotretinoin therapy

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

Committed to Pregnancy Prevention

Reference ID: 3956479

The Pharmacist Guide For the iPLEDGE Program

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For iPLEDGE Program Information

Call Center hours: Monday through Saturday, 9AM–12AM (midnight) EST

1-866-495-0654

www.ipledgeprogram.com

Reference ID: 3956479

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately, and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see **PRECAUTIONS**).

ABOUT ISOTRETINOIN

Isotretinoin is used to treat severe recalcitrant nodular acne. Isotretinoin belongs to a class of drugs known as retinoids, commonly understood to include all natural and synthetic analogues of vitamin A. Therapy with isotretinoin should not be undertaken before conventional treatment has been tried first, including the use of systemic antibiotic therapy, and the patient has been fully counseled about the warnings and precautions in the isotretinoin package insert.

Isotretinoin is teratogenic and must not be used by pregnant women. Women should not become pregnant while taking isotretinoin or for 1 month after therapy is discontinued. A patient who becomes pregnant during treatment should stop taking isotretinoin and immediately contact her prescriber.

Isotretinoin use is associated with other potentially serious adverse events as well as more frequent, but less serious side effects. More frequent, less serious side effects include cheilitis, dry skin, skin fragility, pruritus, epistaxis, dry nose and dry mouth, and conjunctivitis.

Serious Adverse Event Warnings include psychiatric disorders* (depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors). Prescribers should read the brochure *Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin*. Prescribers should be alert to the warning signs of psychiatric disorders to guide patients to receive the help they need. Therefore, prior to initiation of isotretinoin therapy, patients and family members should be asked about any history of psychiatric disorder, and at each visit during therapy patients should be assessed for symptoms of depression, mood disturbance, psychosis, or aggression to determine if further evaluation may be necessary.

Other Serious Adverse Events include pseudotumor cerebri; pancreatitis; hyperlipidemia; hearing impairment*; hepatotoxicity; inflammatory bowel disease; skeletal changes† (bone mineral density changes, hyperostosis, premature epiphyseal closure); and visual impairment (corneal opacities, decreased night vision).

Patients should be reminded to read the Medication Guide, distributed by the pharmacist at the time the isotretinoin is dispensed as required by law.

* No mechanism of action has been established for these events
† The use of isotretinoin in patients 12 to 17 should be given careful consideration especially when a known metabolic or structural bone disease exists

Pregnancy After Isotretinoin Therapy

The terminal elimination half-life of isotretinoin varies but is generally within 10 to 20 hours. The elimination half-life of one of the isotretinoin metabolites, 4-oxoisotretinoin, is approximately 25 hours. Since plasma elimination is host dependent, prescribers should warn patients not to become pregnant for 1 month post treatment. Women who become pregnant during this month should be counseled as to the outcome data. In 1989, Dai et al reported the results of an epidemiologic study of pregnancies that occurred in women who conceived after discontinuing isotretinoin.[1] They studied women from 5 days to more than 60 days between the last dose of isotretinoin and conception. The incidence of birth defects in former isotretinoin patients was not significantly different from the rate in the general population.

Isotretinoin is found in the semen of male patients taking isotretinoin, but the amount delivered to a female partner would be about 1 million times lower than an oral dose of 40 mg. While the no-effect limit for isotretinoin-induced embryopathy is unknown, 20 years of postmarketing reports include 4 with isolated defects compatible with features of retinoid-exposed fetuses; however, 2 of these reports were incomplete, and 2 had other possible explanations for the defects observed.

Birth Defects

There is an extremely high risk that a deformed infant will result if pregnancy occurs while female patients are taking isotretinoin in any amount even for short periods of time. Potentially, any fetus exposed during pregnancy can be affected. Not every fetus exposed to isotretinoin has resulted in a deformed child. However, there are no accurate means of determining which fetus has been affected and which fetus has not been affected.

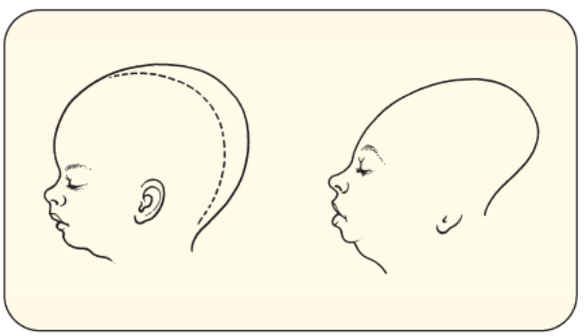
When isotretinoin is taken during pregnancy, it has been associated with fetal malformations, and there is an increased risk for spontaneous abortions and premature birth. **The following human fetal abnormalities have been documented.**

External abnormalities

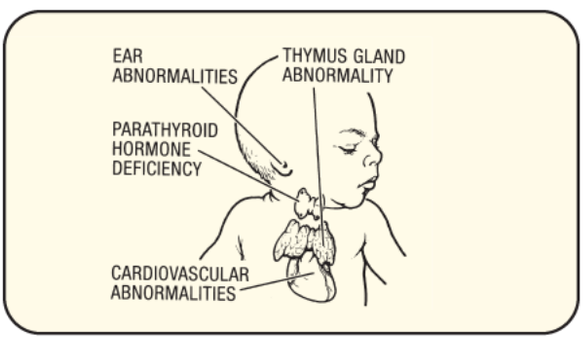
Skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate.

Internal abnormalities

CNS abnormalities including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit; cardiovascular abnormalities; thymus gland abnormalities; parathyroid hormone deficiencies. In some cases death has occurred with certain of the abnormalities noted.



Line drawing represents the possible abnormalities of the low-set, deformed, or absent ears; wide-set eyes; depressed bridge of nose; enlarged head; and small chin.



Line drawing represents the possible abnormalities of the brain, heart, and thymus gland that may occur.

THE iPLEDGE PROGRAM

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE.

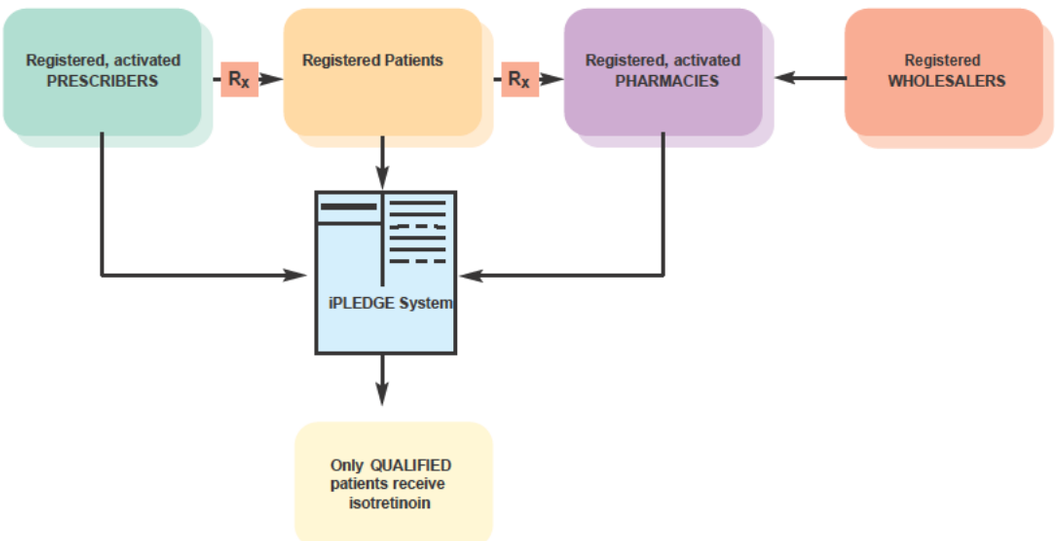
The iPLEDGE Program is a single, shared Risk Evaluation and Mitigation Strategy (REMS) program for prescribing and dispensing all isotretinoin products (brand and generic products) and includes a pregnancy registry.

Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the iPLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the iPLEDGE Program (see PRECAUTIONS).

The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions.

The iPLEDGE Program is a computer-based risk management system that uses verifiable, trackable links between prescriber, patient, pharmacy, and wholesaler to control prescribing, using, dispensing, and distribution of isotretinoin.

The trackable links of the iPLEDGE Program



Non-Compliance Action Policy (NCAP)

The Non-Compliance Action Policy was implemented to monitor compliance, address deviations, and institute appropriate corrective actions to improve minimization of drug exposure during pregnancy and compliance with elements to assure safe use under the iPLEDGE Program. The NCAP sets forth the principles by which Non-Compliance by iPLEDGE Program stakeholders will be evaluated. The NCAP can be found on the iPLEDGE Program website at www.ipledgeprogram.com

Key Features Of The iPLEDGE Program

The iPLEDGE Program has specific requirements for prescribers, patients, pharmacists, and wholesalers. Here is an overview:

- The iPLEDGE Program system tracks and verifies critical program elements that control access to isotretinoin.
- Only prescribers registered with and activated in the iPLEDGE Program can prescribe isotretinoin.
- Prescribers must ensure that all patients—and specifically female patients of reproductive potential—meet the requirements to be registered in the iPLEDGE Program.
- Prescribers and patients must enter required information (i.e., pregnancy test results, 2 forms of contraception used, confirmation of patient counseling) in the iPLEDGE Program system for patients to be qualified to receive a prescription.
- Only patients who are registered by prescribers in the iPLEDGE Program can receive isotretinoin.
- Only pharmacies registered with and activated in the iPLEDGE Program can dispense isotretinoin.
- Pharmacists must access the iPLEDGE Program system to receive authorization to fill and dispense every prescription.
- Manufacturers will only ship to iPLEDGE-registered entities (e.g., direct vendor pharmacies, wholesalers).
- Wholesalers must register annually in the iPLEDGE Program. A registered wholesaler may distribute only FDA-approved isotretinoin product.
- Only wholesalers registered with the iPLEDGE Program can distribute isotretinoin. (See page 9 for information on how to find a registered wholesaler.)
- Registered wholesalers can only ship to wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer or pharmacies licensed in the US and registered and activated in the iPLEDGE Program.
- Telephone, fax, and electronic transmission (e.g., e-mail) prescriptions are permitted in the iPLEDGE Program.

PHARMACIES AND THE iPLEDGE PROGRAM

The iPLEDGE Program includes specific requirements that pharmacies must follow in order to dispense isotretinoin. These include:

- Reviewing and abiding by the Non-Compliance Action Policy (NCAP) (www.ipledgeprogram.com)
- Designating a Responsible Site Pharmacist (*see page 11*)
- Following the procedures to fill and dispense prescriptions (*see page 15*)

Key Information For Pharmacists

- **The Responsible Site Pharmacist must register and activate the pharmacy** in the iPLEDGE Program system.
- **The dispensing pharmacist must get authorization and a Risk Management Authorization (RMA) number** before filling and dispensing prescriptions.
- **Upon receiving authorization, the dispensing pharmacist can fill and dispense a prescription** for a maximum 30-day supply of isotretinoin.
- **Upon authorization, the iPLEDGE Program system** provides the RMA number to the dispensing pharmacist. The pharmacist should document the RMA number.
- **Upon authorization, the iPLEDGE Program system provides a "Do Not Dispense To Patient After"** date to the dispensing pharmacist. This date is calculated as 30 days from the office visit for male patients and females of non-reproductive potential, or 7 days from the pregnancy test date for female patients of reproductive potential. It is recommended that the pharmacist write the date on the sticker and put the sticker on the prescription bag.
- Patients who present a prescription beyond this date will not be authorized in the iPLEDGE Program system to receive isotretinoin.
- **Prescriptions must be obtained by the patient no later than the "Do Not Dispense To Patient After" date, and if not obtained, then the RMA must be reversed in the iPLEDGE Program system and the product returned to inventory.**
- **The iPLEDGE Program system** only authorizes filling and dispensing prescriptions when patients have met the qualification criteria in the system.
- **Prescriptions** that are more than 30 days beyond the date of the office visit (for male patients and females of non-reproductive potential) or more than 7 days beyond the pregnancy test date (for females of reproductive potential) will not be authorized by the iPLEDGE Program system.
- **No automatic refills** are permitted.
- Telephone, fax, and electronic transmission (e.g., e-mail) prescriptions are permitted in the iPLEDGE Program.
- **Isotretinoin** comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.
- An isotretinoin Medication Guide must be given to the patient each time isotretinoin is dispensed, as required by law.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

About Authorization Criteria

Prior to each prescription, the prescriber and patient must enter required patient information into the iPLEDGE Program system. The pharmacist is not responsible for entering this information. When the pharmacist begins the authorization process, the system automatically checks this information to ensure that the patient has met the criteria to receive a prescription. (See page 20 for the specific criteria.)

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THE iPLEDGE Program WEB SITE AND PHONE SYSTEM

The pharmacist can access the iPLEDGE Program system via the program web site and automated phone system:

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The iPLEDGE Program system is used for:

- Activation of the pharmacy registration
- Authorization to fill and dispense prescriptions
- Reversal of approved prescriptions
- Ordering additional copies of *The Pharmacist Guide For the iPLEDGE Program* and patient and professional educational materials
- Finding a wholesaler registered in the iPLEDGE Program
- Finding a pharmacy participating in the iPLEDGE Program
- FAQ's (Frequently Asked Questions)

To log in to either the web site or the phone system, the dispensing pharmacist needs the pharmacy username and password supplied upon registration. The pharmacy's Responsible Site Pharmacist can supply this information.

It is important that the Responsible Site Pharmacist does not forget the iPLEDGE Program username, password, and date of personal significance for the pharmacy. All of these items should be communicated to other pharmacists working at the pharmacy.

(Note: Date of Personal Significance is chosen by you, and can be any date that is easy for you to remember)

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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To Review And Order Materials

You can order additional program materials using either the web site or the phone system as follows:

1. After logging on to the web site, there are two ways to order materials:
   a. Using the navigation menu on the left side of the page, select the "Order Materials" button.

      OR

   b. Using the navigation menu on the left side of the page choose "Pharmacy Information." In the "View Information Online" section, select "To Order Educational Materials, please click here."
2. In the phone system, log in and select the option to "Request Program Information." Additional bag stickers can also be ordered using this process.

To Find A Registered Wholesaler

On the web site, log in and choose "Find Wholesaler" in the left navigation. A list of registered wholesalers and distributors will be presented.

THE RESPONSIBLE SITE PHARMACIST

Each pharmacy in the iPLEDGE Program must designate a pharmacist as the Responsible Site Pharmacist. The Responsible Site Pharmacist is the point of contact for the pharmacy and the iPLEDGE Program. The Responsible Site Pharmacist performs the following tasks:

- Registers the pharmacy with the iPLEDGE Program
- Activates the pharmacy registration initially and annually; attests to program requirements
- Trains all pharmacists who participate in the filling and dispensing of isotretinoin prescriptions and keeps a log or record of the staff who have been trained
- Ensures that all pharmacy staff using iPLEDGE are aware of the pharmacy's username, password and date of personal significance for the iPLEDGE Program System.

Registration

The Responsible Site Pharmacist registers the pharmacy in the iPLEDGE Program. Only one registration is needed for each pharmacy. After the Responsible Site Pharmacist registers the pharmacy, the pharmacy will receive a system password by mail. The NCPDP number is the username for the entire pharmacy.

Activation

Before a pharmacist can fill and dispense prescriptions for isotretinoin, the Responsible Site Pharmacist must activate the registration in the iPLEDGE Program system. The program activation expires annually. The Responsible Site Pharmacist, representing the pharmacy, must activate the automated registration annually to continue ordering, filling, and dispensing isotretinoin. If your activation expires, and you do not intend to reactivate, you must return all unused isotretinoin immediately to the manufacturer or delegate.

The iPLEDGE Program system will report the expiration date of a pharmacy's registration. To retrieve this information on the web site, log in and choose "My Program Status" on the left navigation; in the phone system, log in and select the option to hear "Current Program Status."

Review *The Pharmacist Guide For the iPLEDGE Program* to ensure an understanding of the program. Activation requires attesting to the following statements in the iPLEDGE Program system:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I will train all pharmacists, who participate in the filling and dispensing of isotretinoin prescriptions, on the iPLEDGE Program requirements.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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- I will comply and seek to ensure all pharmacists who participate in the filling and dispensing of isotretinoin prescriptions comply with the iPLEDGE Program requirements described in the booklet entitled *The Pharmacist Guide For the iPLEDGE Program*, specifically the "Key Information for Pharmacists" section including the following dispensing information:
    - **Prescriptions must be obtained up no later than the "Do Not Dispense To Patient After" date, and if not obtained, then the RMA must be reversed in the iPLEDGE Program system and the product returned to inventory.**
- I will only obtain isotretinoin product from only iPLEDGE-registered wholesalers.
- I will not sell, buy, borrow, loan, or otherwise transfer isotretinoin in any manner to or from another pharmacy.
- I will return to the manufacturer (or delegate) any unused product if registration is revoked by the manufacturer or if the pharmacy chooses to not reactivate annually.
- I will not fill isotretinoin for any party other than a qualified patient.

Procedures For Activating In The iPLEDGE System

Access the iPLEDGE Program system to activate the pharmacy's registration via the web site, **www.ipledgeprogram.com**, or the automated phone system, **1-866-495-0654**. Both the web site and the phone system provide prompts to log in and complete the initial activation. Identification in either system requires the username (NCPDP number) and the password received upon registration.

The web site is the faster and easier way to access the system. After initial activation, a pharmacy must re-activate at least annually to remain active in the iPLEDGE Program.

The iPLEDGE Program system will display the "Activate" button on the Pharmacy home page when the activation for a pharmacy is nearing expiration. However, a pharmacy can re-activate at any time using the "Activate Pharmacy Registration" button on the left-hand navigation menu on all pages.

The system requires setting the pharmacy's Date of Personal Significance.

- The date of personal significance is a date that is easily remembered and will be used to verify the pharmacy's identity if required by the iPLEDGE Program system or if the pharmacy's password is lost.
- The same date of personal significance will be used by all pharmacists in the pharmacy when contacting the iPLEDGE Call Center.
- **The date of personal significance should be a date that will be known by all the pharmacists at the pharmacy.**
- It is important that you remember the selected date of personal significance. It is used to verify Pharmacy identity for some functions within the iPLEDGE Program, as well as to obtain assistance from the iPLEDGE Call Center. The

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selected date should be communicated to other pharmacists in your pharmacy that will be using the iPLEDGE Program.

- If you change the date of personal significance for your pharmacy, you should communicate this change to others at your pharmacy that will be using the iPLEDGE Program System.

Using the web site

The Responsible Site Pharmacist:

1. Logs in by entering the pharmacy username (NCPDP number) and password.
2. Changes the pharmacy password and sets the date of personal significance.
3. Selects "Activate Pharmacy Registration" from the Pharmacy home page. The system will provide prompts to complete the activation process. If the current activation for a pharmacy is nearing expiration, the Pharmacy home page will prominently display a direct link to re-activate.

Using the automated phone system

The Responsible Site Pharmacist:

1. At the main menu, selects the option to log in and follows the prompts to enter the pharmacy username (NCPDP number) and password.
2. Changes the pharmacy password and sets the date of personal significance.
3. At the pharmacy menu, selects the option to begin the activation process

Training Pharmacists

The Responsible Site Pharmacist is responsible for the training, and the documentation of training, of all pharmacists in a registered pharmacy. The pharmacy's standard operating procedures for training may be followed in training pharmacists on the iPLEDGE Program requirements.

The training objectives for all dispensing pharmacists include:

- Knowing about isotretinoin teratogenicity and the contraception and program requirements of the iPLEDGE Program
- Being able to access the iPLEDGE Program system and obtain authorization to fill and dispense a prescription
- Correctly using the RMA number and **"Do Not Dispense To Patient After"** date

Training begins by providing *The Pharmacist Guide For the iPLEDGE Program* to all pharmacists. Additional copies can be requested through the automated system.

The Responsible Site Pharmacist should review the following sections with each pharmacist after he/she has read the material:

- Isotretinoin teratogenicity and measures to reduce fetal exposure (*see "About Isotretinoin," page 3*)

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

- Accessing the iPLEDGE Program system via web site and phone system, using username (NCPDP number) and system password (*see page 13*)
- iPLEDGE Program procedures for filling and dispensing prescriptions (*see page 15*)
- Time limitations on dispensing (*see page 16*)
- Prescription bag sticker requirements (*see page 16*)
- Patient qualification criteria (*see page 17*)
- Effective primary and secondary forms of contraception (*see page 19*)
- Additional contraception information and counseling about pregnancy (*see page 22*)

After reviewing the material, the Responsible Site Pharmacist should:

- Review the steps with the pharmacist for accessing the iPLEDGE Program system and the procedures for obtaining authorization to fill a prescription (*see page 15*)
- Ensure that pharmacists have the date of personal significance, username, and password necessary to log in to the iPLEDGE Program system
- Record the date of training, have the pharmacist sign a log or record of training, and co-sign this training record; verification of training records may be requested and reviewed as part of the iPLEDGE Program

To Change The Responsible Site Pharmacist

The pharmacy can change its designated Responsible Site Pharmacist at any time. The new Responsible Site Pharmacist or the former Responsible Site Pharmacist can make the change on the automated phone line, **1-866-495-0654**.

The new Responsible Site Pharmacist:

- Selects the option to continue in English
    - Pharmacy support is only available in English
- Logs in with the pharmacy's username and password
- Selects #0 to transfer to the Call Center, then presses 1 at the prompt
- Selects the option for pharmacies
- The Responsible Site Pharmacist will be connected with an operator, who will assist with the change.
- The new Responsible Site Pharmacist must re-activate the pharmacy in the iPLEDGE Program (for activation information, see page 12)
    - If your activation expires, and you do not intend to reactivate, you must return all unused isotretinoin immediately to the manufacturer or delegate.

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PROCEDURE FOR FILLING AND DISPENSING PRESCRIPTIONS

Access the iPLEDGE system

The dispensing pharmacist:

- Accesses the iPLEDGE Program system via the web site, **www.ipledgeprogram.com** or the automated phone system, **1-866-495-0654**
- Logs in using the pharmacy username (NCPDP number) and the pharmacy password
  - On the web site, chooses "Fill Prescriptions" from the left navigation
  - In the phone system, selects the option to "Obtain Approval to Fill or Reverse a Prescription"
- Enters the patient ID number from the patient ID card
- Enters the patient's date of birth

Confirm patient qualification and obtain authorization

- The iPLEDGE Program system automatically checks patient qualification criteria for you.
- Prescriptions will be authorized only for those patients who meet all criteria.
- If authorized to fill and dispense, the pharmacist enters the:
  - NDC Code
  - Number of days to be dispensed
  - Amount dispensed
- System provides:
  - An RMA number to be documented
  - A **"Do Not Dispense To Patient After"** date. It is recommended that the pharmacist write the date on the sticker and put the sticker on the prescription bag.

Additional strengths for the prescription to achieve the desired dosage can be entered by the pharmacist immediately after the prescription is authorized. If not added immediately, the prescription must be reversed and then re-authorized if the dosage is not correct.

- The pharmacist may proceed with normal insurance adjudication only if the iPLEDGE Program system has authorized dispensing.
- The pharmacist may not proceed with normal insurance adjudication and may not dispense isotretinoin if dispensing is not authorized in the iPLEDGE Program system.
- If not authorized to fill and dispense:
  - The system will provide information or instructions for the patient (e.g., "Please contact your doctor")

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Dispense the prescription

- Only FDA-approved products may be dispensed.
- The system will automatically calculate and provide the **"Do Not Dispense To Patient After"** date to the pharmacist. The pharmacist must not dispense the prescription after this date.
- A maximum 30-day supply of isotretinoin may be dispensed.
- Refills are not allowed. Monthly continuation of therapy requires the patient to satisfy the iPLEDGE Program requirements to obtain a new prescription.

Prescription bag stickers

- The bag sticker has space for the **"Do Not Dispense To Patient After"** date.
- The iPLEDGE Program system provides the **"Do Not Dispense To Patient After"** date.
- The pharmacist should document the date. It is recommended that the pharmacist write the date on the sticker and put the sticker on the prescription bag.
- Additional stickers can be ordered. (*see page 10*)

DO NOT DISPENSE ISOTRETINOIN AFTER THE DATE ON THE BAG STICKER

Non-dispensed prescriptions

If the prescription is not dispensed for any reason (e.g., the patient did not obtain, dispense date expired, third party did not authorize payment, etc.) the authorization to dispense must be reversed in the system. The pharmacist must log in to the web site and select "Reverse Prescription" or call the iPLEDGE Program at **1-866-495-0654**, log in, and select the option to "Obtain Approval to Fill or Reverse a Prescription," or

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iPLEDGE PROGRAM GENERAL INFORMATION

The following section covers general aspects of the iPLEDGE Program.

Determining Reproductive Potential Of Female Patients

The prescriber must determine if a female patient is of reproductive potential before registering the patient in the iPLEDGE Program.

The definition of a female of reproductive potential is a nonmenopausal female who has not had a hysterectomy, bilateral oophorectomy, or documented ovarian failure. This definition includes a young woman who has not yet started menstruating.

A woman who has had a tubal sterilization is considered a female of reproductive potential in the iPLEDGE Program.

Definition of menopause

Menopause can be assumed to have occurred in a woman when there is either:

1. Appropriate medical documentation of prior complete bilateral oophorectomy (i.e., surgical removal of the ovaries, resulting in "surgical menopause" and occurring at the age at which the procedure was performed), OR
2. Permanent cessation of previously occurring menses as a result of ovarian failure with documentation of **hormonal deficiency** by a certified healthcare provider (i.e., "spontaneous menopause," which occurs in the United States at a mean age of 51.5 years).

Hormonal deficiency should be properly documented in the case of suspected spontaneous menopause as follows:

1. If age >54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed;
2. If age <54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

All Patients

To receive isotretinoin, all patients must meet all of the following conditions:

1. ***Must*** be registered with the iPLEDGE Program by the prescriber
2. ***Must*** understand that severe birth defects can occur with the use of isotretinoin by female patients
3. ***Must*** be reliable in understanding and carrying out instructions

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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4. ***Must*** sign a Patient Information/Informed Consent (for all patients) form that contains warnings about the potential risks associated with isotretinoin
5. ***Must*** obtain the prescription within their prescription window as follows:
   - Male patients and female patients who cannot get pregnant, prescriptions must be obtained within the 30-day prescription window, counting the office visit as DAY 1.
   - Female patients who can get pregnant, prescriptions must be obtained within the 7-day prescription window, counting the day of the blood draw or urine sample as DAY 1.
6. ***Must*** not donate blood while on isotretinoin and for 1 month after treatment has ended
7. ***Must*** not share isotretinoin with anyone, even someone who has similar symptoms

All patients should understand that refills are not allowed. Patients can only receive a maximum of 30-day supply of isotretinoin per prescription. For each prescription, continuation of therapy requires the patient to satisfy the iPLEDGE Program requirements to obtain a new prescription. The prescriber must also counsel the patient each month about the iPLEDGE Program requirements and then confirm via the iPLEDGE Program automated system that this counseling occurred.

Females Of Reproductive Potential

Once the prescriber decides to pursue qualification of the patient, a female of reproductive potential must follow these steps.

1. Females of reproductive potential ***must*** have had 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL before receiving the initial isotretinoin prescription. The first test (a screening test) is obtained by the prescriber when the decision is made to pursue qualification of the patient for isotretinoin. There is a 30-day wait period where the patient must be on two forms of birth control simultaneously. The second pregnancy test (a confirmation test) must be done in a CLIA-certified laboratory. The interval between the 2 tests must be at least 19 days.
   - For patients with regular menstrual cycles, the second pregnancy test must be done during the first 5 days of the menstrual period immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.
   - The patient must be using their two forms of birth control for at least 30 days prior to beginning to take isotretinoin, and their second pregnancy test must occur after this 30-day period is complete.
2. The patient must sign the Patient Information/Informed Consent (for all patients) form and the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form.
3. The patient must select and commit to use 2 forms of effective contraception together, at least 1 of which must be a primary form, unless continuous abstinence is chosen. Patients must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy.

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Requirements For Each Prescription

In addition to the requirements for all patients, the female patient of reproductive potential has additional requirements. Prior to each prescription, they must have a negative result from a urine or serum pregnancy test. A pregnancy test must be repeated, in a CLIA-certified laboratory, prior to the female patient receiving each prescription. A pregnancy test must also be obtained at the end of therapy (after the last dose) and 1 month after the last dose. Before each prescription, the iPLEDGE Program also requires monthly counseling about contraception and behaviors associated with an increased risk of pregnancy.

In addition to their required doctor appointments, females of reproductive potential must also report their 2 forms of birth control in the iPLEDGE Program system and answer questions about the iPLEDGE Program and pregnancy prevention.

Effective forms of contraception

Effective forms of contraception include both primary and secondary forms of contraception.

Primary forms	Secondary forms
• Tubal sterilization • Partner's vasectomy • Intrauterine device • Hormonal (combination oral contraceptives, transdermal patch, injectables, implantables, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier form (used with or without spermicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

Unacceptable forms of contraception

- Progesterone-only "mini-pills"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield‡

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Abstinence

For this program, all females of reproductive potential must fully commit to pregnancy prevention. Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE Program who are or have been sexually active. Abstinence may be appropriate when it is a lifestyle choice (e.g., religious practice) and not just a social circumstance (e.g., not having a current partner). If, after counseling, a sexually active patient chooses abstinence without contraception, she must understand that isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program. All females of reproductive potential must receive contraception counseling.

Patient Criteria For Authorization To Fill And Dispense

This is the information that must be entered by prescribers and patients into the iPLEDGE Program system for all patients and, specifically, for females of reproductive potential. This is the information the system uses to authorize filling a prescription and to provide the RMA number and the **"Do Not Dispense To Patient After"** date.

All patients

Prescriber confirms that:

- The patient is registered with the iPLEDGE Program
- The patient was counseled about the iPLEDGE Program requirements

Females of reproductive potential

Prescriber:

- Confirms that the patient was counseled about the iPLEDGE Program contraception requirements
- Enters the 2 forms of contraception that the patient is using
- Enters pregnancy test results to start the 7-day prescription window, counting the date of the specimen collection as DAY 1.

Patient:

- Correctly answers the questions about pregnancy prevention and the iPLEDGE Program
- Enters the 2 forms of contraception she is using

The primary form of contraception reported by both the prescriber and the patient must match.

Note: The system will automatically provide the pharmacist with the "Do Not Dispense To Patient After" date.

Note: the following is provided to the pharmacist for information purposes only. No action is required by the pharmacist for a patient to fulfill the requirements of the iPLEDGE Program and become qualified to obtain a prescription.

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All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient, as

Female patients who can get pregnant…	Male patients and female patients who cannot get pregnant…
The prescription window is 7 days and starts on the date that the urine or blood sample is taken for a pregnancy test. This date is counted as DAY 1. To determine the end date of their 7-day prescription window, these patients should add 6 days to the date of the blood or urine sample being taken.	The prescription window is 30 days and starts on the date that the prescriber enters as the date of the office visit. This date is counted as DAY 1. To determine the end date of their 30-day prescription window, these patients should add 29 days to the date of their office visit.

After 11:59 p.m. Eastern Time on the last day of the prescription window, the prescription can no longer be obtained and the patient must start the process over to get a new prescription window.*

* There are generally no restrictions regarding the timing of office visits. One notable exception is that females of reproductive potential who do not obtain their first month of therapy prescription in their first 7-day prescription window, must wait at least 19 days from their most recent pregnancy test until getting their next pregnancy test. **This is based on the requirement that the most recent pregnancy test prior to beginning therapy must be conducted in the first 5 days of her menstrual cycle.**

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

ADDITIONAL CONTRACEPTION INFORMATION

The iPLEDGE Program has *The iPLEDGE Program Prescriber Contraception Counseling Guide* available. This is the professional companion piece to the patient's *iPLEDGE Program Birth Control Workbook*. Copies can be requested through the iPLEDGE Program system. (See page 10 for instructions.)

Patients can also be directed to the phone system for confidential birth control information. They can call **1-866-495-0654**, log in, and select the option to hear "Confidential Birth Control Information."

The following subjects are covered:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Counseling A Potentially Pregnant Patient

If a patient expresses concern that she may be pregnant, tell her to stop taking isotretinoin immediately and call her prescriber.

Males And Birth Defects

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.[2]

Isotretinoin also has not been shown to affect a male's ability to father children. Studies did not show effects on sperm count, how sperm look, or how well they swim and move. (For more information, see page 4.)

REFERENCES

1 Dai WS, Hsu M-A, Itri LM Safety of pregnancy after discontinuation of isotretinoin *Arch Dermatol* 1989;125:362-355

2 Centers for Disease Control and Prevention Birth defects: frequently asked questions Available at: http //www.cdc.gov/ncbddd/bd/faq1.htm#Whatisabirthdefect Accessed August 8, 2005

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For More Information About Isotretinoin

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

For iPLEDGE Program Information

Call Center hours: Monday through Saturday, 9AM–12AM (midnight) EST

1-866-495-0654

www.ipledgeprogram.com

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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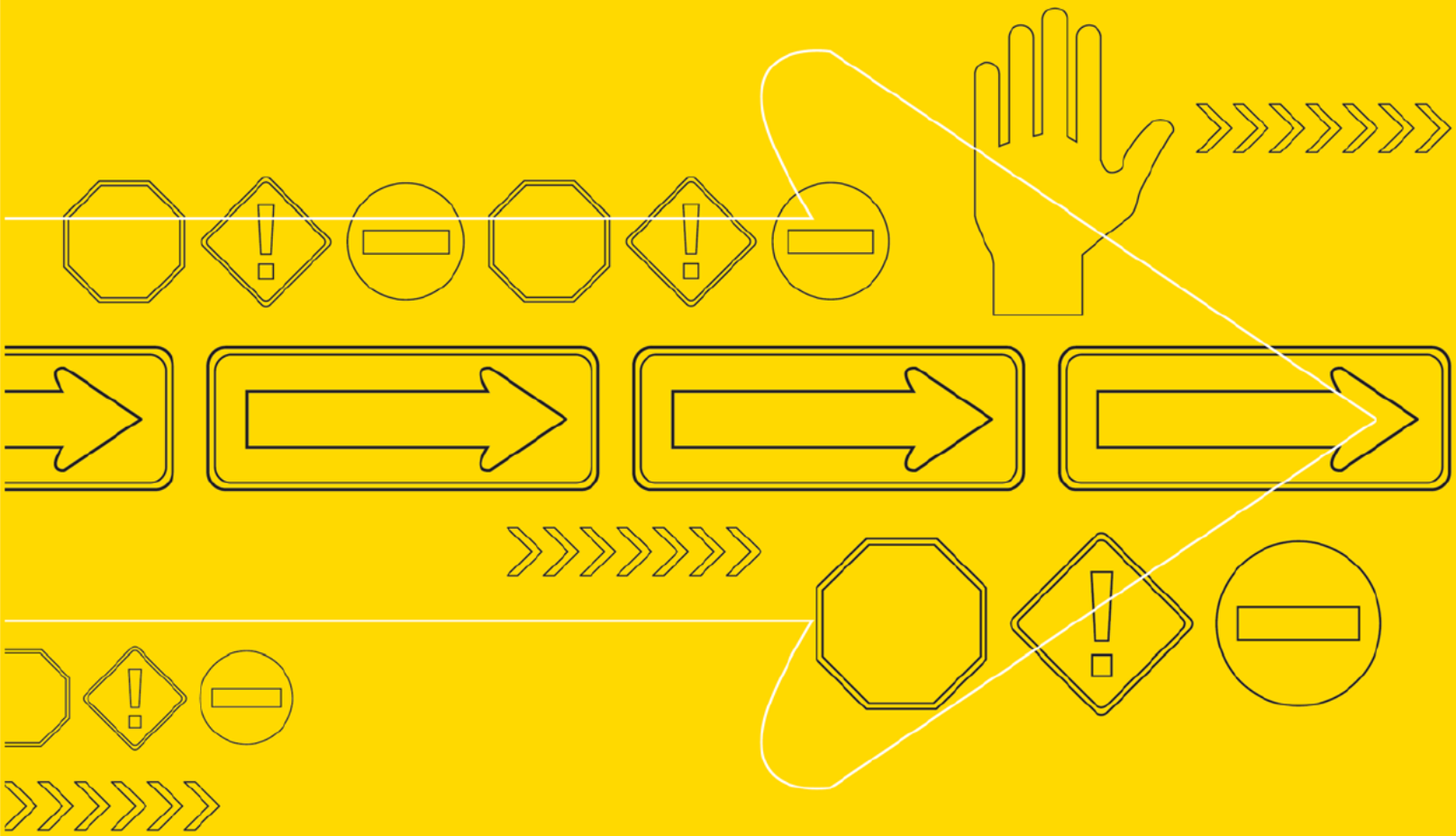

www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

Committed to Pregnancy Prevention

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iPLEDGE™
Committed to Pregnancy Prevention

Welcome
Have Questions? Call our toll-free number 1-866-495-0654
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY

- HOME
- PATIENT INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- PRESCRIBER INFORMATION
- Find a Participating Pharmacy
- FAQs / How to's

Pharmacy Registration

Please provide your pharmacy's NCPDP number and click the Lookup Info button. This will be used as your Username to identify you in the program and for you to login to the iPLEDGE system using the phone or internet site.

NCPDP Number [ ] Lookup Info

Enter or confirm your information

** denotes required field*

Responsible Site Pharmacist First Name * Responsible Site Pharmacist Last Name*

Responsible Site Pharmacist License *

Phone* Fax

Email

Preferred Method of Communication*

Provider Information

Provider

Add

Provider ID

Remove

☐ This pharmacy orders isotretinoin directly from one or more of the manufacturers of isotretinoin

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

Save and Print

Privacy Statement Safety Notice Non-Compliance Action Policy © 2005 iPLEDGE

Pharmacy Registration

Please provide your pharmacy's NCPDP number and click the Lookup Info button. This will be used as your Username to identify you in the program and for you to login to the iPLEDGE system using the phone or internet site.

NCPDP Number [ ] [Lookup Info]

Enter or confirm your information

** denotes required field*

Responsible Site Pharmacist First Name * Responsible Site Pharmacist Last Name*

Responsible Site Pharmacist License *

Phone* Fax

Email

Preferred Method of Communication*

Provider Information

Provider

[Add]

Provider ID

[Remove]

☐ This pharmacy orders isotretinoin directly from one or more of the manufacturers of isotretinoin

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

[Save and Print]

Pharmacy Registration Print Page

iPLEDGE™
Committed to Pregnancy Prevention

Have Questions? Call our toll-free number **1-866-495-0654**
VLWeb01/VAL: Monday to Saturday, 9 AM - 12 AM (Midnight) ET

Pharmacy Registration

Send To
iPLEDGE - Committed to Pregnancy Prevention
PO BOX 29094
PHOENIX AZ 85038-9978

Or Fax to
1-866-495-0660

Your information

NCPDP Number 8110025

RSP iPLEDGE P 12312123

Phone 555-555-1212 Fax
Email iPLEDGEPH@test.unc
Preferred communication method Email

Your providers

☐ This pharmacy orders isotretinoin directly from one or more of the manufacturers of isotretinoin

RSP Signature _____ Date _____

Return to Home Page

Most Recent Modification: July 2016

The iPLEDGE Program

Patient Introductory Brochure

The important information you need to know about isotretinoin and the iPLEDGE program before starting treatment

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Reference ID: 3956479

Are you thinking about taking isotretinoin (eye-soh-tret-in-OH-in) for acne? Read this brochure to learn more about isotretinoin and the iPLEDGE Program.

Reference ID: 3956479

Isotretinoin treats a type of severe acne called nodular acne. It is used after other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin. The iPLEDGE Program requires birth control for female patients who can get pregnant for at least 1 month before, during, and 1 month after stopping treatment and pregnancy tests before, during, and after treatment.

Before starting isotretinoin, you should know about its other serious side effects. Talk with your doctor about how bad your acne is and how isotretinoin can help your skin.

Decide if isotretinoin is right for you. Your doctor will ask you to read and sign forms that say you understand the serious risks of isotretinoin. It is important for you to know how to take isotretinoin correctly and what to expect.

WHAT IS THE iPLEDGE PROGRAM?

The iPLEDGE Program is a set of steps all patients, doctors, and pharmacists must follow. The main goal is preventing pregnancy and birth defects, but both male patients and female patients must follow the iPLEDGE Program. The iPLEDGE Program is a single, shared Risk Evaluation and Mitigation Strategy (REMS) program for prescribing and dispensing all isotretinoin products (brand and generic products) and includes a pregnancy registry.

To get isotretinoin, all patients must:

- Sign the Patient Information/Informed Consent form(s)
- Be able to keep appointments
- Agree to follow the iPLEDGE Program steps

WHAT DO MALE PATIENTS NEED TO KNOW ABOUT THE iPLEDGE PROGRAM?

- Talk with your doctor about the iPLEDGE Program and the possible side effects of taking isotretinoin.
- Keep your appointments. You must be able to see your doctor for your prescriptions. Treatment usually lasts 4 to 5 months.
- Each prescription is for up to a maximum 1-month supply.

WHAT DO ALL FEMALE PATIENTS NEED TO KNOW ABOUT THE iPLEDGE PROGRAM?

Are you a female patient who can get pregnant? This includes all female patients who have menstrual periods. It includes young female patients who have not started having menstrual periods. Even a female patient who has had her tubes tied can still get pregnant.

If you are able to get pregnant, you need to know how to keep from becoming pregnant. Your doctor has information to help you learn about effective birth control for the iPLEDGE Program.

You would not have to follow the birth control requirements of the iPLEDGE Program if:

- You have stopped having periods for 12 months in a row (menopause) and your doctor says you are in menopause
- You had both of your ovaries or uterus taken out by surgery
- Your ovaries do not work and you cannot get pregnant (confirmed by your doctor)
- You commit to not having any sexual contact with a male at any time for at least 1 month before, during, and 1 month after your last dose

Reference ID: 3956479

WHAT DO FEMALE PATIENTS WHO CANNOT GET PREGNANT NEED TO KNOW ABOUT THE iPLEDGE PROGRAM?

- Talk with your doctor about the iPLEDGE Program and the possible side effects of taking isotretinoin.
- Keep your appointments. You must be able to see your doctor for your prescriptions. Treatment usually lasts 4 to 5 months.
- Each prescription is for up to a maximum 1-month supply.

WHAT DO FEMALE PATIENTS WHO CAN GET PREGNANT NEED TO DO FOR THE iPLEDGE PROGRAM?

Plan For Your Isotretinoin Treatment

- Talk with your doctor about the iPLEDGE Program and the risks of isotretinoin for unborn babies.
- Keep your appointments. You must be able to see your doctor for your prescriptions and to get monthly pregnancy tests. Treatment usually lasts 4 to 5 months.
- Each prescription is for up to a maximum 1-month supply.

Choose 2 Effective Forms Of Birth Control

- Not all birth control is acceptable for the iPLEDGE Program. Not all forms of birth control can be used together.
- Learn what birth control will work for the iPLEDGE Program. Choose 2 forms that you really will use together.
- Even if you are already using birth control, get this information from your dermatologist, gynecologist, family doctor, or a birth control expert. The iPLEDGE Program will pay for a visit for you to learn about birth control.

Use The 2 Effective Forms Of Birth Control Together

- You must use both forms together all the time for at least 1 month before you start taking isotretinoin.
  - There is a 30-day mandatory waiting period during which you must be using both chosen forms of birth control before you are eligible to begin treatment with isotretinoin
- You must use both forms together while you are taking isotretinoin
- You must use both forms together for 1 month after isotretinoin treatment.

Get BIood 0r Urine Tests For Pregnancy

You must have a negative pregnancy test:

- To enter the iPLEDGE Program
- Before you start isotretinoin
- Performed in an approved lab each month before you can obtain your prescription
- Right after you finish your last isotretinoin dose
- 1 month after you finish your last isotretinoin dose

Each Month Before You Can 0btain Your Prescription

- Your doctor must enter your pregnancy test results in the iPLEDGE Program system
- You must access the iPLEDGE Program system to answer different questions about the iPLEDGE Program and confirm the 2 forms of birth control that you are using.

Talk with your doctor about the iPLEDGE Program. This information does not replace talking with your doctor about acne or your treatment. If you have any questions, write them down. Ask your doctor before starting isotretinoin. Be sure you understand the answers to all your questions.

REVIEW: THE KEY INFORMATION FOR THE iPLEDGE PROGRAM – FEMALE PATIENTS WHO CAN GET PREGNANT

Before You Start Treatment

- Learn about isotretinoin and the iPLEDGE Program.
- Plan for office visits.
- Get birth control information. Choose 2 iPLEDGE Program acceptable forms of birth control.
- Start using both forms of birth control together all the time for at least 1 month before starting isotretinoin.
- Have 2 negative pregnancy tests.
  - The first in order to get registered in the iPLEDGE Program, which may be performed in the doctor's office.
  - The second before you actually start isotretinoin, performed by an approved lab during the first 5 days of your menstrual period.
- Sign the Patient Information/Informed Consent form(s).
- Get a prescription from your doctor.
- Before you obtain the prescription, access the system to answer questions about the iPLEDGE Program and preventing pregnancy. You can answer your questions after your doctor has entered your pregnancy test result in the iPLEDGE Program system.
- Obtain your prescription for up to a maximum of a 1-month supply.
- Obtain your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1.

Each Month During Treatment

- Use 2 forms of birth control together all the time.
- Get a prescription for up to a maximum of a 1-month supply.
- Have a negative pregnancy test, performed in an approved lab.
- Answer questions about the iPLEDGE Program and preventing pregnancy. You can answer your questions after your doctor has entered your pregnancy test result in the iPLEDGE system.
- Obtain your prescription for up to a maximum of a 1-month supply and within the 7-day prescription window counting the date of the pregnancy test as DAY 1.
- Do not donate blood.

After Your Last Dose

- Have a pregnancy test after your last dose.
- Use 2 forms of birth control together all the time for 30 more days.
- Have a last pregnancy test 1 month after your last dose, performed in an approved lab.
- Do not donate blood for 30 days after taking your last dose.

Reference ID: 3956479

REVIEW: THE KEY INFORMATION FOR THE iPLEDGE PROGRAM – MALE PATIENTS AND FEMALE PATIENTS WHO CANNOT GET PREGNANT

Before You Start Treatment

- Learn about isotretinoin and the iPLEDGE Program.
- Plan for office visits.
- Sign the Patient Information/Informed Consent form.
- Get a prescription from your doctor.
- Obtain your prescription for up to a maximum of a 1-month supply.
- Obtain your prescription within the 30-day prescription window counting the date of the office visit as DAY 1.

Each Month During Treatment

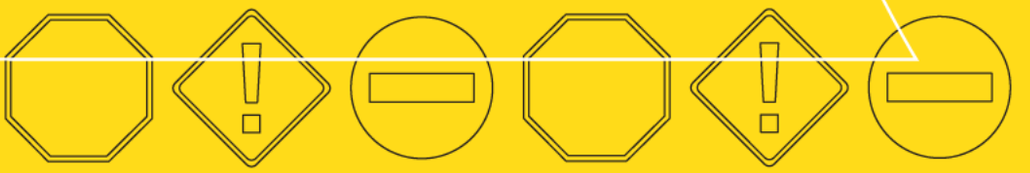
- Get a prescription for up to a maximum of a 1-month supply.
- Obtain your prescription for up to a maximum of a 1-month supply and within the 30-day prescription window counting the office visit as DAY 1.
- Do not donate blood.

After Your Last Dose

- Do not donate blood for 30 days after taking your last dose.

Safety Information

ABOUT ISOTRETINOIN



WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
   Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
     Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

Reference ID: 3956479

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do **not** take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. **You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE system, go to **www.ipledgeprogram.com** or call **1-866-495-0654.**

Reference ID: 3956479

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

Reference ID: 3956479

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

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Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children.**

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call the iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.

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NOTES:

NOTES:

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

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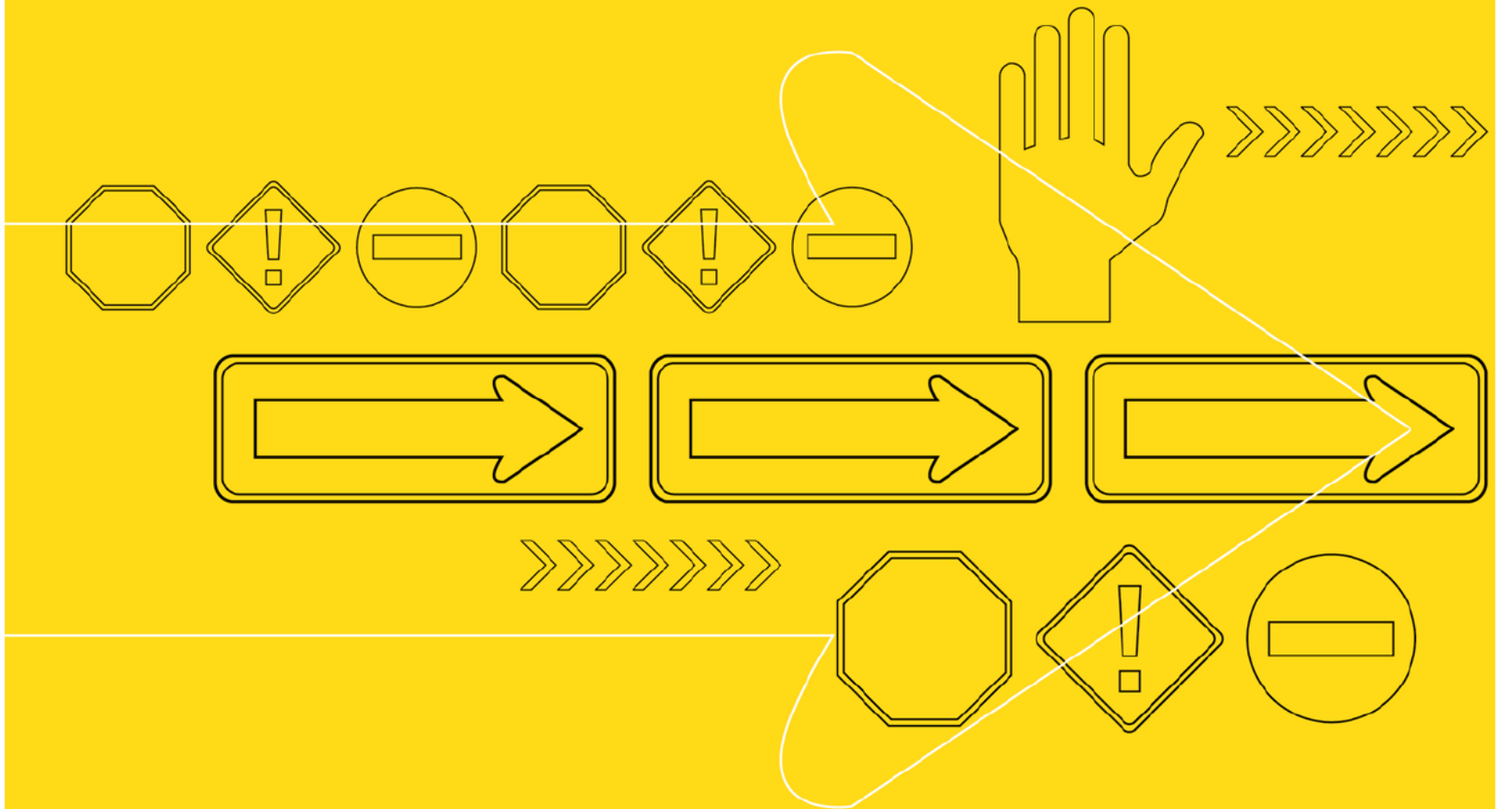

www.ipledgeprogram.com 1-866-495-0654

WARNING

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Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

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Most Recent Modification: July 2016

The iPLEDGE Program

Isotretinoin Educational Kit For Female Patients Who Can Get Pregnant

The Importance Of Avoiding Pregnancy On Isotretinoin

The tools you need to help you prepare, plan treatments, and prevent pregnancies during the course of isotretinoin treatment

WARNING

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- Guide To Isotretinoin For Female Patients Who Can Get Pregnant
- Birth Control Workbook
- Contraception Referral Form And Contraception Counseling Guide
- Patient Identification Card
- Patient Information/Informed Consent (for all patients)
- Patient Information/Informed Consent About Birth Defects (for females who can get pregnant)
- Patient Flowchart

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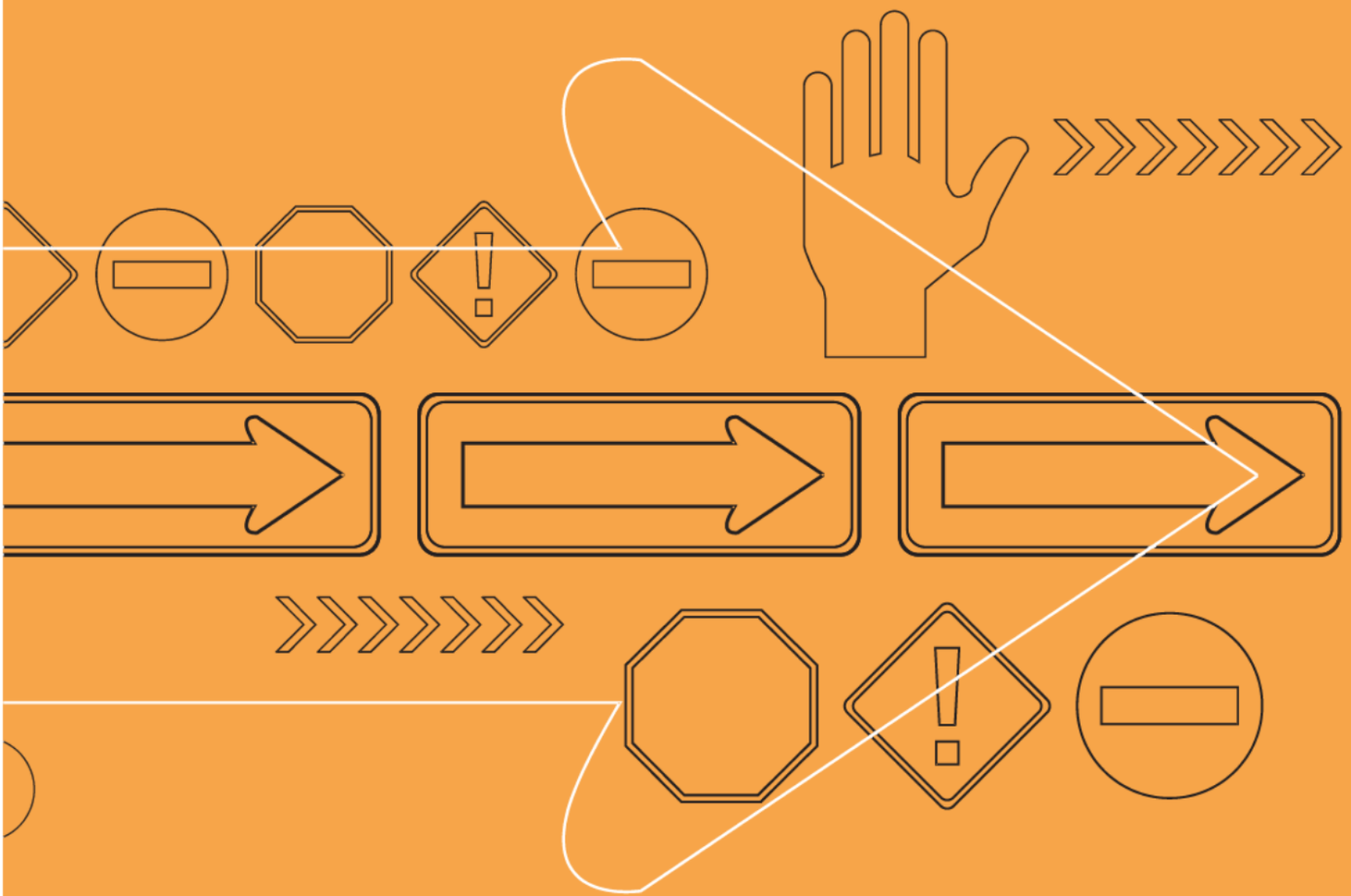
Reference ID: 3956479

Guide To Isotretinoin For Female Patients Who Can Get Pregnant



The guide to help you prepare, plan treatments, and prevent pregnancies during the course of isotretinoin treatment

Reference ID: 3956479

Most Recent Modification: July 2016

The iPLEDGE Program

Guide To Isotretinoin For Patients Who Can Get Pregnant

The Importance Of Avoiding Pregnancy On Isotretinoin

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iPLEDGE™
Committed to Pregnancy Prevention

Reference ID: 3956479

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ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin. The program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and the other materials in this educational kit. Your doctor also has an educational video for you to watch.

Make sure you understand the requirements of the iPLEDGE Program. Then, decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR FEMALE PATIENTS WHO CAN GET PREGNANT

Here are 2 key messages of the iPLEDGE Program:

Do NOT take isotretinoin if you are pregnant.

Do NOT get pregnant before starting isotretinoin, while taking it, and for 1 month after your last dose.

If you get pregnant while taking isotretinoin, there is a very high chance that your baby will be deformed, born too early, or die before being born. This can happen even if you only take isotretinoin for a short time.

Prevent Pregnancy And Birth Defects

Here are some key steps you must follow in the iPLEDGE Program to take isotretinoin:

Have 2 negative pregnancy tests before you start isotretinoin.

Have a negative pregnancy test before you obtain each monthly prescription.

Use 2 forms of birth control together.

Reference ID: 3956479

You must use 2 forms of birth control together correctly all the time for 1 month before you start isotretinoin, while you are taking isotretinoin, and for 1 month after your last dose. These forms of birth control must be effective in the iPLEDGE Program.

Any form of birth control can fail. Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.

Your doctor will talk with you about birth control or refer you to a gynecologist, a family doctor, or a birth control expert for counseling.

Reasons you would not have to use 2 forms of birth control

There are 2 reasons you would not have to use 2 effective forms of birth control.

- You commit to not having any heterosexual sexual intercourse with a male for 1 month before, during, and for 1 month after your isotretinoin treatment (abstinence).
- You are unable to get pregnant because:
  - You have entered menopause, and your doctor has confirmed this.
  - You have had both of your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant woman receives blood that you donated. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 14 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

Reference ID: 3956479

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant and your patient educational kit are resources for the information you need about isotretinoin and the iPLEDGE Program. The iPLEDGE Program also has a web site and an automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE Program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID card, and other program materials. You use these to log in to the system *(see page 9)*. You will use the system to meet some of the monthly requirements of the program.

After you have been registered in the iPLEDGE Program by your doctor, you will receive your iPLEDGE password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE Program system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant explains the key information about the iPLEDGE Program before, during, and after your isotretinoin treatment. Here is a general overview:

1. Learn about the iPLEDGE Program and the isotretinoin side effects and risks in pregnancy.
2. Sign the Patient Information/Informed Consent forms.
3. Plan for treatment and for monthly appointments and pregnancy tests.
4. Choose 2 forms of effective birth control for the iPLEDGE Program; use them all of the time.
5. Take blood or urine pregnancy tests.
6. Answer monthly educational questions to show you understand the iPLEDGE Program and about preventing pregnancy.
7. Follow requirements for pregnancy testing and follow-up after your last dose.
8. Do not donate blood during your treatment or for 1 month after your last dose.
9. Do not share isotretinoin.

This information and details of the program are described in the sections to follow. The section on page 6 reviews the forms of effective birth control in the iPLEDGE Program.

You can always use the checklist on the next page as a quick reminder of the program information.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient

Female patients who can get pregnant…

The prescription window is 7 days, and starts on the date that the urine or blood sample *is taken for your pregnancy test. This date is counted as DAY 1.*

To determine the end date of your 7-day prescription window, you should add 6 days to the date of the blood or urine sample being taken.

After 11:59 p.m. Eastern Time on the last day of the 7-day prescription window, you can no longer obtain your prescription, and must start the process over to get a new 7-day prescription window.

All patients have a specific period of time in which they can Obtain their prescription.

Before Starting Treatment

PLANNING

- ❑ **Plan** your course of treatment (about 4 to 5 months). (*see page 8*)
- ❑ **Talk** with your doctor about the iPLEDGE Program.
- ❑ **Sign** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Have** your first urine or blood pregnancy test, which can be performed at the doctor's office.
- ❑ **Get** your patient ID cards containing your patient ID number from your doctor. (*see page 8*)

BIRTH CONTROL (*see page 6*)

- ❑ **Read** *The iPLEDGE Program Birth Control Workbook*.
- ❑ **Talk** with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options.
- ❑ **Choose** 2 effective forms of birth control.
- ❑ **Start** using the 2 forms of birth control together for at least 1 month before you start isotretinoin.

YOUR FIRST PRESCRIPTION

- ❑ **Have** a second pregnancy test within the first 5 days of your menstrual period (at least 30 days after registration).
- ❑ **Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form. (*see page 9*)
- ❑ **Answer** questions about the iPLEDGE Program and confirm your 2 forms of birth control. (see page 10) This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.
- ❑ **Obtain** your prescription for up to a maximum of a 1-month supply. (*see page 11*)
- ❑ Obtain your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1. (*see page 12*)
  - If you are not able to obtain your first prescription within the 7-day prescription window, you will be required to wait a minimum of 19 days before you can start this process again.
- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ Answer different questions each month about the iPLEDGE Program.

During Treatment

- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **Confirm** your 2 forms of birth control by entering them into the iPLEDGE Program System. (see page 10)
- ❑ **Answer** different questions each month about the iPLEDGE Program. **This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- ❑ **Obtain** your prescription for up to a maximum of a 30-day supply. *(see page 11)*
- ❑ **Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1. (*see page 12*)
  - If you do not obtain your prescription within the 7-day prescription window, you will need to go back to your doctor to start this process again.
- ❑ **Do not donate** blood.

After Treatment

RIGHT AFTER YOUR LAST DOSE (*see page 13*)

- ❑ **Get** a pregnancy test after your last dose.
- ❑ **Continue** using your birth control for 1 month.
- ❑ **Do not donate** blood for 1 month after your last dose.
- ❑ **Ensure** that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

1 MONTH AFTER YOUR LAST DOSE

- ❑ **Have** a final pregnancy test at 1 month after your last dose.
- ❑ Ensure that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

EFFECTIVE FORMS OF BIRTH CONTROL

Not all forms of birth control are acceptable while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read The iPLEDGE Program Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read *The iPLEDGE Program Birth Control Workbook*. Discuss this information with someone you trust. Discuss it with your partner. Think about what forms of birth control you would really use, and then talk with your doctor or a birth control expert.

Talk With An Expert

If you want to talk to a birth control expert, your gynecologist, or family doctor about birth control, the doctor who prescribes isotretinoin for you can refer you. The makers of isotretinoin will pay for a visit for you to talk about birth control. *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* is in this booklet.

- Make an appointment with a birth control expert, your gynecologist, or family doctor.
- Take *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* with you. It has important information that the birth control expert, gynecologist, or family doctor needs to talk about, including the forms of effective birth control for the iPLEDGE Program.
- The healthcare professional providing contraception counseling will fill out the Contraception Referral Form included in the guide after he/she talks with you and then mail or fax it back to the doctor who prescribes your isotretinoin.

Changing Your Birth Control

If you need to change forms of birth control during your isotretinoin treatment, you need to tell the doctor who prescribes your isotretinoin. You do not want to take isotretinoin if you are not protected against pregnancy all the time.

You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been on the new form for at least 1 month and have a negative pregnancy test.

Changing From Abstinence

If you have been abstinent (not having any sexual activity) and you decide to start having sexual activity, you must tell the doctor who prescribes your isotretinoin. You and your doctor must make a plan to start birth control and be sure you are not pregnant before you continue isotretinoin.

One of the most common reasons that women get pregnant is that they do not avoid sexual activity when they plan to be abstinent.

Video: *Be Prepared, Be Protected, And Be Aware: The Risk Of Pregnancy While On Isotretinoin*

Your doctor has a video that shows the kinds of birth defects that may happen if a woman takes any amount of isotretinoin while she is pregnant. It also reviews the steps for preventing pregnancy.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST INFORMATION

Plan Your Course Of Treatment

Birth Control and Pregnancy tests

Before you can begin isotretinoin therapy, there is a 30-day wait period where you must be on two forms of birth control. Additionally, you need to have 2 negative pregnancy tests. They can be urine or blood tests. You will need to plan with your doctor when and where to take your pregnancy tests.

- You take the first test when you decide to take isotretinoin.
- You take the second test during the first 5 days of the menstrual period right before you start isotretinoin. This pregnancy test must be done by an approved lab. The interval between the two tests must be at least 19 days.

You also take a pregnancy test every month done by an approved lab during treatment. You also take a pregnancy test after your last dose, and 1 month after your last dose. You will need to plan with your doctor when to take your pregnancy test each month.

Prescriptions

The most isotretinoin you can get at any one time is up to a maximum of a 30-day supply. You will need to see your doctor each month to get a new prescription, and meet the monthly program requirements.

Get Your Patient ID Number And Cards

Your doctor will give you your patient ID number and cards when you start the iPLEDGE Program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. It is important not to lose these cards. Write your number down as soon as you receive it and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled at the pharmacy
- When you log in to the iPLEDGE Program automated system, either the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**

Reference ID: 3956479

About The iPLEDGE Program Automated System

The first time you login to the iPLEDGE Program (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using the iPLEDGE Program system.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can obtain up your prescription
- Change to a new doctor
- Get information about isotretinoin
- Answer your Comprehension Questions, required before you can obtain your prescription
- View information about your current status, your 7-day prescription window, and next steps required in the program
- View FAQ's (Frequently Asked Questions)

If you lose your patient ID cards, and cannot remember your patient ID number, contact your doctor.

Informed Consents

You sign 2 consent forms to be in the iPLEDGE Program.

1. **Patient Information/Informed Consent (for all patients)**

Signing the Patient Information/Informed Consent (for all patients) form means you understand that there are risks with isotretinoin.

2. **Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)**

Your doctor will talk to you about the risks of isotretinoin during pregnancy. You must also get this information in writing. You must understand that a baby exposed to isotretinoin could have severe birth defects. Signing the consent form means the following:

- You understand the risks of isotretinoin for unborn babies.
- You agree to use 2 effective forms of birth control, as the iPLEDGE Program requires. *The iPLEDGE Program Birth Control Workbook* has the list of effective forms.

Reference ID: 3956479

The iPLEDGE Program Pregnancy Registry

Because isotretinoin causes such severe birth defects, it is very important for us to know about all the pregnancies that happen during treatment and within 1 month after the last dose. If you think you are pregnant call your doctor. The confidential iPLEDGE Program Pregnancy Registry is a way to collect that information. It may help us prevent more pregnancies in the future.

Your doctor will tell you about the confidential iPLEDGE Program Pregnancy Registry. You are encouraged to contact the iPLEDGE Program Pregnancy Registry at 1-800-681- 7247 if you get pregnant.

Answering Questions About The iPLEDGE Program And Preventing Pregnancy

The iPLEDGE Program requires you to answer comprehension questions before obtaining every prescription. These questions will demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. **You will not be able to answer your questions until your doctor has entered your pregnancy test result in the iPLEDGE Program System.** You may not obtain up your prescription until you have correctly answered the questions. You may use your iPLEDGE Program educational kit as a resource as you answer the questions.

Your First Month Taking Isotretinoin

The first month that you answer your questions, you will be asked a series of questions about iPLEDGE Program information and counseling provided to you. There are no wrong answers to these questions. The answers are used to determine how often the iPLEDGE Program materials are shared with patients.

Birth Control Verification

You must enter the 2 forms of birth control you are using. Your doctor will also separately enter the 2 forms of birth control you told him or her you are using. This information must be in the iPLEDGE Program system and must match for you to obtain your prescription.

Comprehension Questions

Before each prescription can be obtained from the pharmacy, you will have different questions about the iPLEDGE Program and preventing pregnancy to answer. You answer the questions in the iPLEDGE Program system using the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654** within the 7-day prescription window.

You can use *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and *The iPLEDGE Program Birth Control Workbook* to help you with the answers.

You need your patient ID number and password to log in to the iPLEDGE Program system.

To answer questions on the iPLEDGE Program web site:

1. Log in
2. Click on the button under "Answer the Questions"
3. Enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

To answer the questions on the iPLEDGE Program phone system:

1. Log in
2. Select the option to "Demonstrate Your Program Knowledge"
3. Follow the prompts to enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

The system will let you know if you answered correctly. If you missed any questions, you will get to try other questions like the ones you missed. You must answer the questions correctly before you will be able to obtain your prescription.

If you miss a question again, the system will tell you where to look in *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* or *The iPLEDGE Program Birth Control Workbook* to find answers. You can answer the questions again later. You may also talk with your doctor about questions you missed.

Obtain Your Prescription

Obtain your isotretinoin prescriptions only from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com**, has a list of registered and activated pharmacies. Log in and choose "Finding a Participating Pharmacy" on the Patient home page.

The pharmacist will contact the iPLEDGE Program system before filling the prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only obtain your prescription for isotretinoin if:

- Your pregnancy test was negative
- Your doctor entered your 2 forms of birth control in the iPLEDGE Program system

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- You answered your questions correctly. **This can only be done after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- You also entered your 2 forms of birth control

You **obtain** the prescription within the 7-day prescription window (1 week) of the date of your pregnancy test, counting the date of the pregnancy test as DAY 1.

To figure out the last date you can obtain your prescription, add 6 to the date of your pregnancy test. For example:

Day 1 pregnancy test	Day 2 – Day 6	Day 7 – Last day obtain Day of the up prescription
(Friday, March 1)	(Saturday–Wednesday)	(Thursday, March 7)

The 7-day prescription window expires at 11:59 p.m. Eastern Time on Day 7 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 7-day prescription window expires before you obtain your prescription, you can start a new 7-day prescription window right away (unless it is your first prescription window), but you must repeat the program requirements to get another prescription. Additional information regarding the specific dates of your 7-day prescription window, and other information about your current status can be found by selecting "My Program Status" on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479

After Your Last Dose

It is very important that you:

- Get a pregnancy test.
- Keep using 2 effective forms of birth control together all the time for 1 month after your last dose. It takes time for isotretinoin to leave your bloodstream.
- Go back to your doctor 1 month after your last dose for your last pregnancy test, even if you think you are not pregnant. If you miss this appointment, you will receive a reminder notification.
- Do not give blood for 1 month after your last dose.
- If your doctor does not enter the results of the pregnancy test after your last dose, and does not enter the pregnancy test 1 month after your last dose, both you and your doctor will be contacted for additional information.

Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE Program system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE Program web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**. You need your patient ID number to log in to the system.

To change your doctor on the iPLEDGE Program web site:

1. Log in
2. Choose "Change Primary Prescriber" from the menu
3. You need to enter the following information about your new doctor:
   - First and last name
   - City
   - Phone number

To change your doctor on the automated phone line:

1. Log in
2. Select the Option for "More Choices"
3. Select the Option to "Change Your Prescriber"
4. Follow the prompts to enter the new information

The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE Program system before being able to give you a prescription.

Reference ID: 3956479

Safety Information

ABOUT ISOTRETINOIN

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
   Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
     Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

Reference ID: 3956479

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule. Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do not take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control. To access the iPLEDGE Program system, go to www.ipledgeprogram.com or call 1-866-495-0654.

Reference ID: 3956479

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

Reference ID: 3956479

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Reference ID: 3956479

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children**.

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.

Reference ID: 3956479

For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, ask your doctor, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call the automated phone line at **1-866-495-0654**.

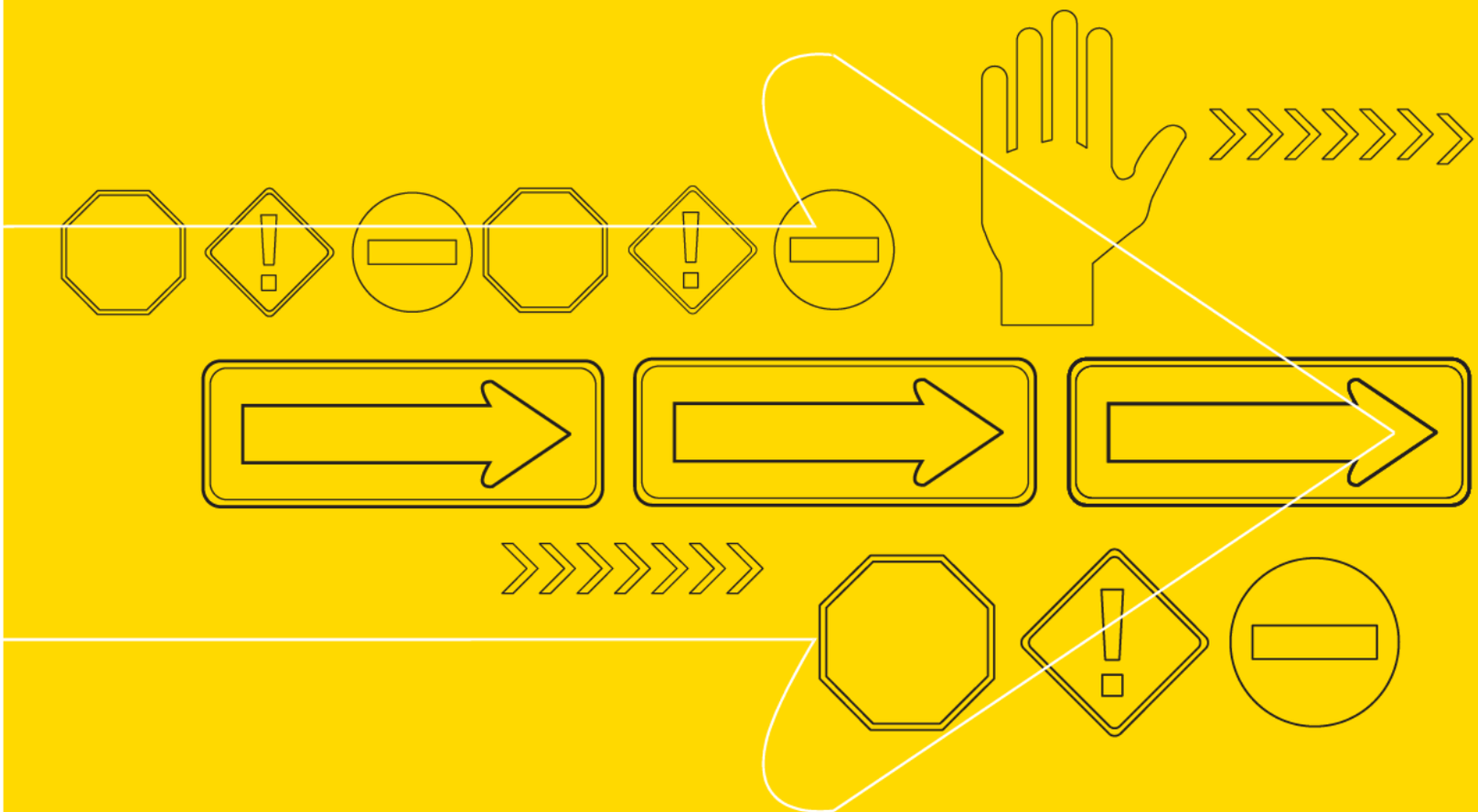
For private birth control information, you can reach the iPLEDGE Program automated phone line 24 hours a day, 7 days a week at 1-866-495-0654. You can learn about different subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Committed to Pregnancy Prevention

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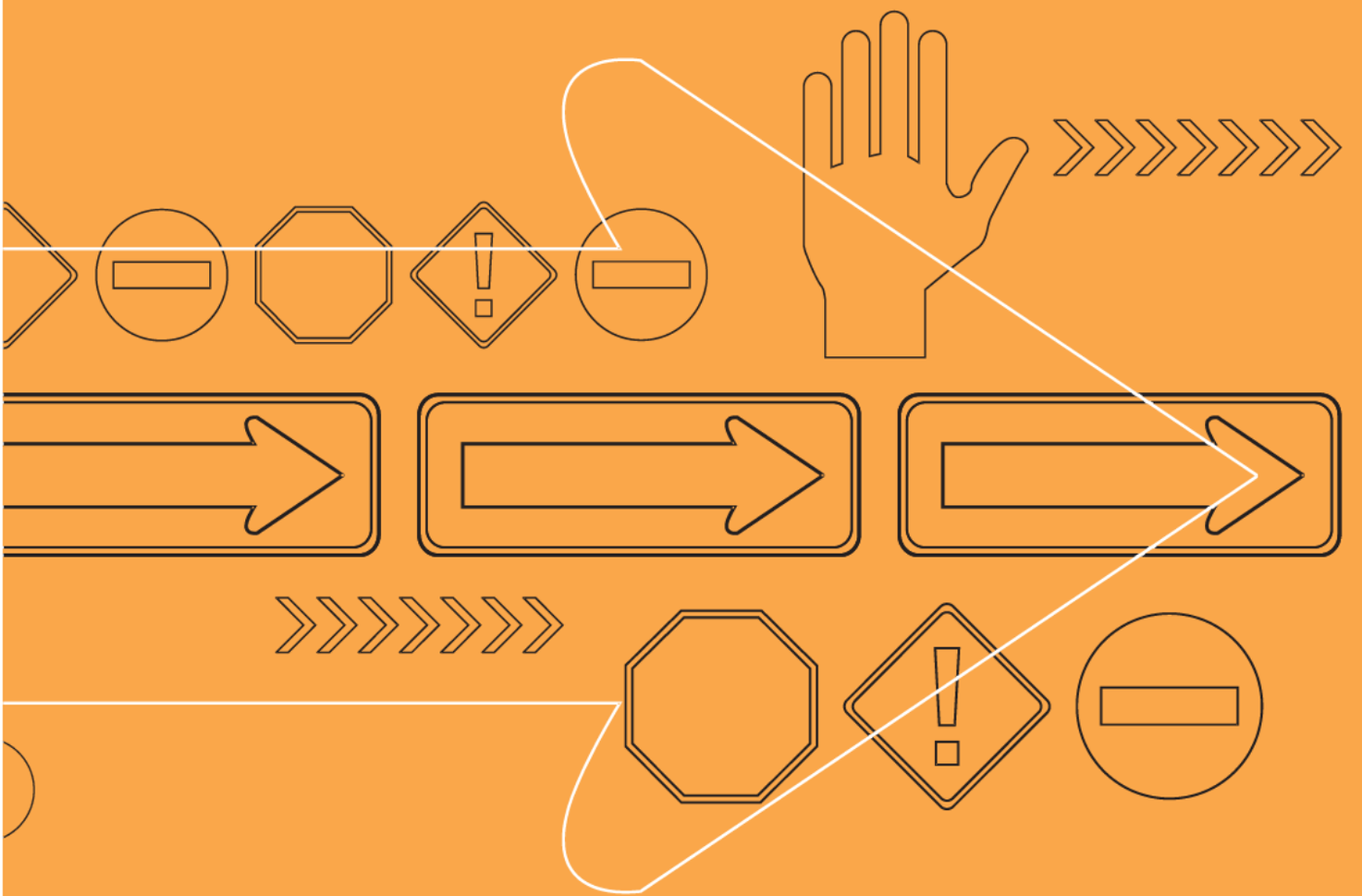
Reference ID: 3956479

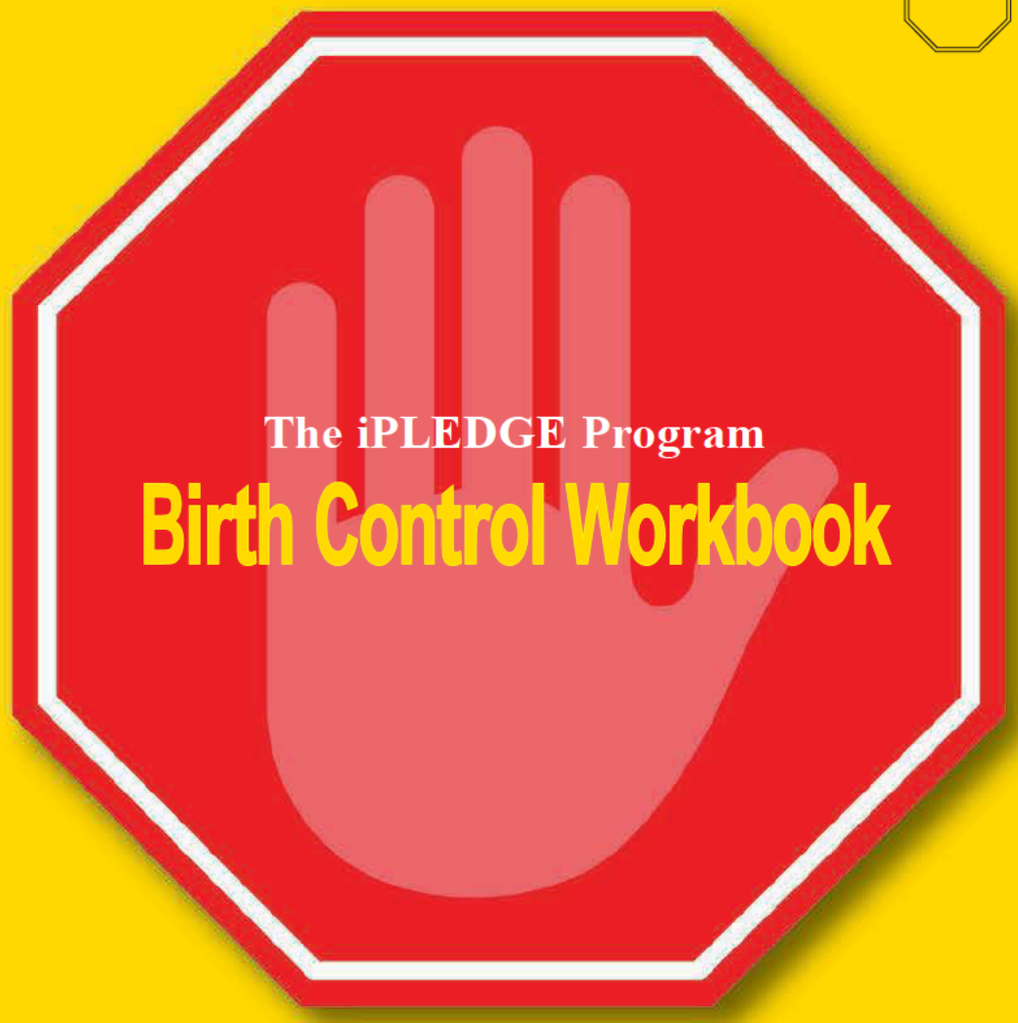
Birth Control Workbook



The guide to help you decide which forms of birth control are best for you

Reference ID: 3956479

Most Recent Modification: July 2016



The iPLEDGE Program

Birth Control Workbook

The guide to help you decide which forms of birth control are best for you during treatment with isotretinoin

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

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The iPLEDGE Program Birth Control Workbook

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PREVENTING PREGNANCIES

Not all forms of birth control are effective while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read This Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read this *iPLEDGE Program Birth Control Workbook*. Read it before you make any decisions about birth control. Read it even if you are already using birth control. Read it even if you think you will not have sex with a male for your whole isotretinoin treatment.

After you have read through the booklet, talk it over with someone you trust. Think about what kinds of birth control you would really use. Then talk with your doctor or a birth control expert.

Share this workbook with your partner. Talk with your partner about birth defects and isotretinoin. Explain what you both need to do to prevent pregnancy. Tell him you need to prevent pregnancy for at least 1 month before you start isotretinoin, during your treatment, and for 1 month after your last dose. This can be several months.

Write down a list of questions for your dermatologist, gynecologist, or family doctor. No question is too silly. Make sure you know how to use the birth control forms you choose.

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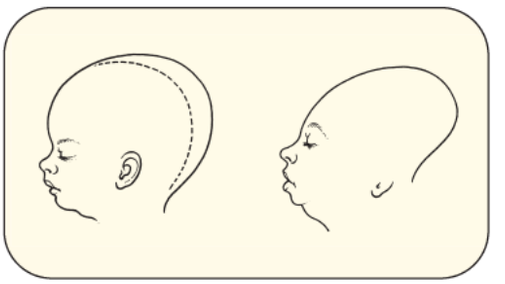
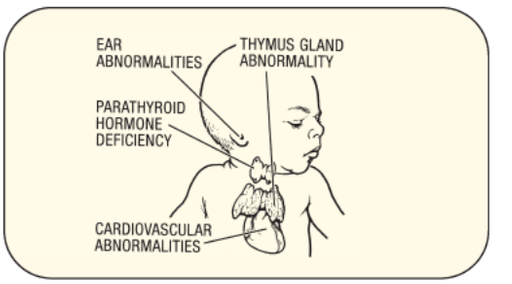
WHY SHOULD I USE THIS WORKBOOK?

You are getting ready to start isotretinoin (eye-soh-tret-in-OH-in). It treats severe acne, but it can also cause birth defects. You must not get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose. **There is a very high chance that your baby could be deformed, born too early, or die.** This can happen even if you take isotretinoin for only a short time.





The pictures show some of the birth defects your baby can have. Your baby's head could be deformed; the ears could be an odd shape or even missing. The eyes could be too far apart, the bridge of the nose too low, or the chin smaller than normal. The baby could have mental retardation or severe problems in the glands, heart, and brain.

You do not want to be pregnant or get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose.

To keep from getting pregnant, you need to use 2 effective forms of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- While you take it—treatment usually lasts 4 to 5 months
- For 1 month after your last dose—you still need protection against pregnancy

This workbook is for ALL female patients who can possibly get pregnant. This means that:

- You are physically able to get pregnant
- You have a uterus and ovaries
- You have menstrual periods

Even if you are not having sex, you still need to follow the requirements of the iPLEDGE Program.

Female Patients Who Cannot Get Pregnant

Female patients who cannot get pregnant are not required to be on birth control. This applies to you if:

- You have entered menopause, and your doctor has confirmed this.
- You have had your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

HOW SHOULD I USE THIS WORKBOOK?

Use this workbook as a guide to help you decide which 2 effective birth control forms are best for you during your treatment. You will want to pick a birth control form that works for you and gives you the best protection against pregnancy (primary form). Since all forms of birth control can fail, you must also pick a second form (another primary form or a secondary form) that you use every time you have sex.

This workbook also provides information about abstinence, emergency birth control, and issues around conception and pregnancy.

THE iPLEDGE PROGRAM AND BIRTH CONTROL

Referral for birth control counseling

Before beginning treatment, you or the doctor may choose a referral to a birth control expert. The makers of isotretinoin will pay for 1 visit for birth control counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the birth control requirements and the effective forms of birth control of the iPLEDGE Program for the birth control expert. The referral form should be taken with you to the birth control counselor.

Why Do I Have To Use 2 Forms Of Birth Control Together?

- Any single birth control form can fail.
- Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.
- Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control!

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Can I Use Any 2 Forms Of Birth Control?

No, you must choose from the iPLEDGE Program list of effective birth control forms.

The 2 types of birth control you use for the iPLEDGE Program are called **primary forms** and **secondary forms**.

- **Primary forms** do not fail very often. Be sure to choose a primary form that gives you the lowest chance of failure. This depends on such things as how well you remember to take medicine every day, whether you have had children or your partner has had a vasectomy, or you have medical problems.
- **Secondary forms** include **barrier forms** and **other forms** of birth control. The most important thing about a secondary form is using it every time you have sex.
  - **Barrier forms** keep sperm from entering the uterus. Barrier forms include the diaphragm and the cervical cap, both of which must be used with a cream that kills sperm, called a spermicide. The Male Latex Condom is also a Barrier form, and it can be used with or without spermicide.
  - **Other forms** (vaginal sponge) contain spermicide.

Preventing Pregnancy By Abstinence (Not Having Sex)

Abstinence means that you ***will not have sex*** or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do, especially if you are used to having sex.

It is easier not to have sex when it is a lifestyle choice, such as religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence).

If you cannot commit completely to not having sex (abstinence) while taking isotretinoin, you must use 2 separate, effective forms of birth control at the same time. The only exceptions are if you have had surgery to remove your uterus (a hysterectomy) or both of your ovaries (bilateral oophorectomy), or if your doctor has medically confirmed that you are post-menopausal. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.

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Concerns About Birth Control Pills

Many female patients use birth control pills. But birth control pills can fail, and you can get pregnant. They fail because you may forget to take them as directed by your health care provider.

- If you take them about the same time every day, they are very effective birth control.
- If you miss pills and do not take them every day, your chance of getting pregnant is much higher with birth control pills than with other primary birth control forms, such as hormonal shots or an intrauterine device (IUD).

If you are taking birth control pills, do you remember to take them every day? If not you need to consider another primary form of birth control as you read this workbook.

The iPLEDGE Program Effective Birth Control Forms

Effective forms of contraception include both primary and secondary forms of contraception:

Primary forms	Secondary forms
• Tubal sterilization (tying your tubes) • Partner's vasectomy • Intrauterine device • Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier form (used with or without spermicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

You cannot use 2 hormonal forms together. Progesterone-only "mini-pills" are not considered an effective form of birth control for the iPLEDGE Program.

Female condoms are not an effective secondary form of birth control for the iPLEDGE Program.

Birth Control Forms That Are NOT Acceptable

You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

- Birth control pills without estrogen (progesterone-only mini-pills)
- Female condoms
  - *A thin, loose-fitting, and flexible plastic tube that you put inside your vagina. It covers your cervix to block sperm.*
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
  - *This means not having sex during certain times of the month when you might be more likely to get pregnant. It does not work.*
- Withdrawal
  - *Your partner can leak enough sperm to get you pregnant even if he does not ejaculate inside you.*
- Cervical shield[‡]
  - *A silicone disc that sticks to your cervix to keep sperm out.*

Tell your doctor what type of birth control you are using. You will need to change to effective forms if your birth control is listed above. You must use 2 effective forms together all the time for at least 1 month and have a negative pregnancy test.

[‡] A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception See page 28

Reference ID: 3956479

Ask yourself:

1. Which of the following is NOT one of the effective primary or secondary forms of birth control while taking isotretinoin?
   - A) Partner's vasectomy or tubal sterilization (tying your tubes)
   - B) Natural family planning
   - C) Hormonal IUD
   - D) Cervical cap with spermicide

2. Which of the following are effective forms of birth control for someone on isotretinoin?
   - A) The hormonal skin patch and a male latex condom
   - B) Cervical cap and a male latex condom
   - C) Copper T380A IUD and withdrawal
   - D) Birth control pills and a diaphragm with spermicide

Answer key: page 38

WHY DO I NEED HELP CHOOSING BIRTH CONTROL?

Not every birth control form is good for everyone. Some female patients should not use certain birth control, such as hormones or an IUD. If you are not good at remembering to take medicines, you should not choose birth control pills. Your dermatologist, gynecologist, or family doctor will help you choose the right forms for you. They will also give you exact instructions on how to use them.

Choose forms that you will actually use all the time. Some female patients have found it hard to use 2 forms of birth control together all the time. **This workbook will help you sort through these questions.** It will help you choose the 2 birth control forms that will be best for you. Here are some questions to think about.

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Ask yourself:

- Have you ever used birth control? Did you think you will need to use birth control someday?
- What birth control are you using now? Do you like it and want to continue using it?Is it on the list of effective birth control for the iPLEDGE Program?
- Are you currently having sex?
- Are you ever pressured into sex or think you may be forced to have sex?
- If you are taking birth control pills, do you ever forget to take them? Do you ever take them out of order? Do you always take medications the way you are told?
- Are there any forms of birth control you have heard about and would like to try?
- Can you rely on your partner's cooperation when using birth control, such as getting him to use a male latex condom each time you have sex?
- Are you worried about protecting yourself from STIs (sexually transmitted infections) or HIV (AIDS)?
- Is the cost of birth control a problem for you?
- Do you mind having to stop sex play to use a male latex condom or diaphragm?
- Do you worry about certain forms of birth control?
- Do you ever want to be pregnant?

What If I Cannot Use 2 Forms Of Birth Control Together All The Time?

Talk with your dermatologist, gynecologist, or family doctor. If you plan to have sex during your treatment and feel you cannot be 100% successful in using 2 forms of birth control each time, you should not take isotretinoin.

What If My Birth Control Fails?

The section on "Emergency Birth Control (Emergency Contraception)" is on page 31 of this workbook. It tells you what emergency birth control is and where to get it quickly.

Reference ID: 3956479

MAKING A CHOICE ABOUT BIRTH CONTROL

General Advice

Stay with your current primary form of birth control if:

- You are currently using an effective primary form AND you use it perfectly. For example, you do not miss birth control pills or hormone shots.
- You are satisfied with it.

Talk with your dermatologist, gynecologist, or family doctor about changing birth control before you start isotretinoin treatment if you:

- Do not use your current form of birth control perfectly. For example, you forget to change hormonal skin patches every week.
- Are not satisfied with the birth control you are using now. Changing birth control in the middle of your isotretinoin treatment is difficult.

You need to tell the doctor who prescribes your isotretinoin if you decide to change forms of birth control during treatment. You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been using the new form with a second form for at least 1 month and have a negative pregnancy test.

Planning Ahead With Your Partner

You want your partner to support you as you go through isotretinoin treatment. It is a great idea to talk with him about the iPLEDGE Program before you start. Do not surprise him later.

1. Talk to him about why you decided to take isotretinoin at this time.
2. You will want him to agree with and support your decision to have this treatment.
3. Make sure he knows all the facts about isotretinoin and birth defects. Show him the patient information. Your partner needs to understand all the facts about isotretinoin. He needs to be aware of what good it can do, as well as its risks.
4. Make sure he knows you have to use 2 forms of birth control together correctly all the time for at least 1 month before beginning isotretinoin treatment, during treatment for several months, and 1 month after the last dose of isotretinoin.
5. Make sure he is willing to go along with the iPLEDGE Program for several months.

You could ask your partner:

1. To help you make a list of questions to ask your doctor
2. To come with you to a doctor's office visit
3. To help you choose the 2 forms of birth control you will be using

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Ask yourself:

1. Your doctor tells you that you need to have a pregnancy test before you can obtain a prescription. You would:
   - A) Refuse the test because you know you are not pregnant
   - B) Ask your doctor to explain why you need the test
   - C) Go to another doctor to get isotretinoin

2. I need to use 2 separate, effective forms of birth control at the same time while on isotretinoin because:
   - A) There is a high chance for multiple births from taking isotretinoin
   - B) There is a very high chance that my baby will be deformed if I get pregnant
   - C) I may find it hard to not have sex during treatment and 1 month after my last dose

3. You already take birth control pills. If you want to start isotretinoin, you:
   - A) Review this *iPLEDGE Program Birth Control Workbook*, and then get counseling before you choose a second form
   - B) Do not worry about a second form now, because you are not having sex with anyone

Answer key: page 38

PRIMARY FORMS OF BIRTH CONTROL

This section of the workbook provides information about the different forms of primary birth control. It only gives you the most important information you need for the iPLEDGE Program. It does not cover all the side effects or other information about these forms. If you want more information, ask your dermatologist, gynecologist, or family doctor. They have more information written for healthcare professionals and for patients.

None of the primary forms protect against sexually transmitted infections (STIs) or HIV (AIDS).

Hormonal Birth Control Forms

Hormonal birth control forms include combination birth control pills, the skin patch, shots, under-the-skin implants, and the vaginal ring. They are prescription medicines that prevent pregnancy.

Reference ID: 3956479

Hormonal Combination Birth Control Pills

Hormonal combination birth control pills are birth control pills you take by mouth every day as prescribed.

Progesterone-only birth control pills (mini-pills) are not acceptable for the iPLEDGE Program because they are not an effective form of birth control. If you are using these, you will have to choose another primary form of birth control.

Who should not take birth control pills?

You should not use birth control pills if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

Why is it important how I take birth control pills?

Birth control pills provide very good protection only if you take them about the same time every day and do not miss any pills. If you miss pills, your chance of pregnancy is much greater. Your chance of getting pregnant is higher if you miss pills at the beginning of your cycle or start your pills too late in your cycle. Less than half of all females take their birth control pills as prescribed.

- The most important thing about using birth control pills as your primary form of birth control is taking them every day to keep the chance of pregnancy as low as possible. If you have not used them perfectly, you may need to choose another primary form of birth control, such as the hormonal shot, an IUD, or a hormonal skin patch.
- Isotretinoin may make birth control pills less effective. That means you could be more likely to get pregnant while you are taking isotretinoin, particularly if you miss a pill.

Are you taking birth control pills now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you ever have pills left at the end of the month?
- How often do you miss more than 1 pill per cycle? Do you do it more than 2 cycles in a year?
- Have you ever taken birth control pills out of order?

If you answered yes to any of these questions, you probably need to choose another primary form of birth control.

If you are not taking birth control pills now, why do you think you want to try them? Ask yourself:

- Have you ever had to remember to take a pill every single day?
- Why do you think you can remember this task?

If you do not remember to take your pill every day without fail or have never taken pills every day before, you should probably not use birth control pills during isotretinoin treatment.

Advantages

- You may be able to get pregnant within 3 months after stopping birth control pills.
- Breast cysts may occur less frequently
- May provide some protection against the development of uterine and ovarian cancer

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Disadvantages

- Birth control pills do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- If you skip pills, your chance of pregnancy is very high.
- Isotretinoin, antibiotics, and St. John's Wort may make birth control pills less effective.

What should I do if I miss birth control pills when I am on isotretinoin?

If you miss any birth control pills, do not have sex for the rest of your cycle. You could get pregnant.

- If you miss 1 pill, take it as soon as you remember. Continue taking your other pills at the regular time. Call your doctor as soon as you realize it.
- If the whole day goes by before you realize you missed a pill, it is OK to take 2 pills together.
- **If you miss more than 2 days, you should call your doctor as soon as you realize it.** You are at a greater chance for pregnancy if you start a cycle late or miss taking pills during the first week of each cycle.

Reference ID: 3956479

Ask yourself:

1. If your 2 birth control forms are birth control pills and the diaphragm with spermicide, and you forgot to take 2 pills in a row, you should:
   - A) Not worry because you are using a diaphragm with spermicide, too
   - B) Not have sex and call your doctor because you do not have enough protection to keep from getting pregnant
   - C) Take birth control pills 2 at a time until you catch up

2. You are talking to your doctor about having your second pregnancy test, so you can start isotretinoin. You have been on birth control pills for 1 month, and it is the second day of your period. Three days ago, you and your partner forgot to use a male latex condom when you had sex. You should:
   - A) Have the pregnancy test anyway because it will tell you if you are pregnant
   - B) Not worry because you have your period
   - C)Tell the doctor you and your partner forgot to use a male latex condom once
   - D) Not worry because you forgot before and never got pregnant

Answer key: page 38

Hormonal Skin Patch

The hormonal skin patch is a thin, plastic patch that you put on your skin. It releases female hormones into your body to protect against pregnancy.

Who should not use the hormonal skin patch?

You should not use the patch if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal skin patch?

You put a new patch on each week for 3 weeks. The fourth week is patch free, usually the time that you have a menstrual period. You place the hormonal skin patch where you can check it easily—on the upper outer arm, stomach, or upper body—but NOT on your breasts.

Reference ID: 3956479

Are you using the hormonal skin patch now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you have trouble remembering to change the patch each week? Has the patch ever come loose or fallen off and you did not immediately put on another one?
- Have you gained weight so that you weigh close to or more than 200 pounds?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using the hormonal skin patch, why do you think you would change to it?

Advantages

- It is not necessary to remember to take a daily pill.
- Many patients have more regular, lighter and shorter periods.

Disadvantages

- The patch does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If it becomes loose or falls off for more than 24 hours, you can get pregnant.
- If you leave the same patch on more than 1 week, you can get pregnant.
- Common side effects include breakthrough bleeding, nausea and vomiting, headaches and breast tenderness.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.
- Possible increased risk of blood clots. Please discuss this with your doctor.

Reference ID: 3956479

Hormonal Vaginal Ring

The hormonal vaginal ring is a small flexible ring that you put into your vagina once a month. It releases female hormones into your body and works like birth control pills.

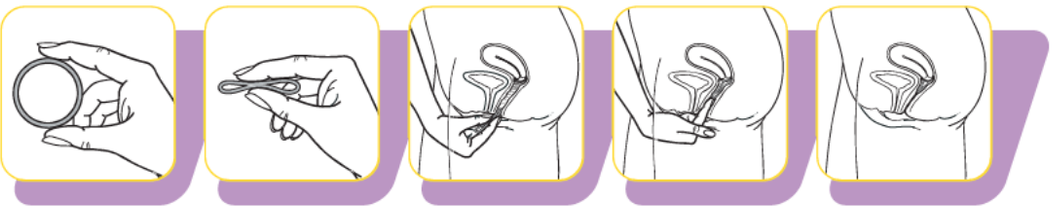
Who should not use the hormonal vaginal ring?

You should not use the hormonal vaginal ring if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal vaginal ring?

You put a new ring in your vagina once every 4 weeks on the same day of the week. You leave it there for 3 weeks and then take it out. During the one-week break, you usually have a menstrual period. **If the ring slips out of the vagina during the 3-week period, you must replace it within 3 hours.**



Are you using the hormonal vaginal ring now?

If you are, is this going to be your primary form of birth control?
Before you decide, ask yourself:

- Do you have trouble remembering to remove the ring after 3 weeks?
- Has the ring ever slipped out and you did not notice?
- Do you have trouble inserting the ring?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using a hormonal vaginal ring, why do you think you would change to it?

Reference ID: 3956479

Advantages

- It is not necessary to remember to take a daily pill.
- It does not need to be fitted by a doctor.
- Many female patients have more regular, lighter, and shorter menstrual periods.
- Your ability to have children returns quickly after stopping the ring.

Disadvantages

- The ring does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- You cannot use it with a diaphragm or cervical cap.
- Some medicines for a vaginal yeast infection increase the level of hormones released into the blood.
- You may have trouble inserting the ring.
- Pregnancy can happen if:
  - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
  - The ring slips out of the vagina and you do not replace it within 3 hours
  - The ring does not stay in the vagina for 3 weeks
  - You leave the ring in the vagina for more than 3 weeks
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.

Hormonal Shots—Single Hormone

Single hormonal shots use a progestin (a female hormone) to prevent pregnancy. They keep you from releasing eggs, keep eggs from growing in the uterus, and make it harder for sperm to get to an egg.

Who should not take single hormonal shots?

You should not take single hormonal shots if you have any unexplained vaginal bleeding, have or had breast cancer, have liver problems or are pregnant.

How do I take single hormonal shots?

Your dermatologist, gynecologist, or family doctor can give you a shot in your arm, belly, or buttocks once every 12 weeks.

Reference ID: 3956479

Are you taking single hormonal shots now?

- If yes, is this going to be your primary form of birth control? How often do you miss shots?
- If you are not getting single hormonal shots, why do you think you would change to them?

Advantages

- A single shot works for 12 weeks at a time.
- There is no daily pill to take.
- You can use it if you cannot take the hormone estrogen.

Disadvantages

- Single hormonal shots do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- They may cause thinning or loss of bone and should not be used for more than 2 years.
- They may cause irregular bleeding.
- If you are planning to get pregnant AFTER you finish your isotretinoin treatment, it may take up to 18 months to get pregnant after you stop getting single hormonal shots.

How soon does the single hormonal shot start to work?

If you get the shot within the first 5 days of your menstrual flow, the protection against pregnancy begins right away.

Hormonal Intrauterine Device

The hormonal IUD is a small piece of plastic your doctor puts into your uterus. The hormonal IUD has a progestin (female hormone) that keeps you from releasing eggs and slows down sperm.

Who should not use a hormonal IUD?

Some of the reasons women should not use the hormonal IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; problems with your immune system; leukemia; AIDS; IV drug abuse; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus.

Reference ID: 3956479

How do I use a hormonal IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The hormonal IUD can stay in place for up to 5 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Do you have a hormonal IUD now?

If you do, is this going to be your primary form of birth control? First, ask yourself these questions:

- Is the IUD in place? Can you feel the string?
- When did you last have it checked by your clinician? It needs to be checked within 3 months after you had it inserted.
- If you are not using a hormonal IUD, why do you think you would change to it?

Advantages

- It is a good choice for long-term birth control (5 years), and you may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps and heavy and longer menstrual periods for the first few months after it is placed, and increased chance of infection.
- Your body may push out the IUD. This can happen without your knowing it. This occurs mostly during a woman's menstrual period.
- You must check for the strings after each menstrual period to make sure the IUD is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Reference ID: 3956479

Ask yourself:

1. You have an IUD inserted as your choice for a primary form of birth control. Which of the following can you use as a second form?

   A) Male latex condoms with or without spermicide

   B) Hormonal shots

   C) Cervical cap without spermicide

   D) Diaphragm with spermicide

   E) Mini-pills (e.g., progesterone-only birth control pills)

   F) All of the above

Answer key: page 38

Hormonal Implants (Under-The-Skin)

Implantable birth control is a plastic rod(s), the size of a matchstick that is put under the skin in the upper arm by a healthcare provider in the office. It is effective for up to three years.

Who should not use

You should not use implantable birth control if you:

- Are pregnant
- Have or have had a current or past history of clots
- Have or have had liver disease
- Have or have had breast cancer
- Are allergic to anything in the implant

How do I use

The implant is put under the skin by a healthcare provider in the office. It generally cannot be seen once under the skin and once in, is effective for up to 3 years. It can be removed at any time by a procedure done by the healthcare provider in the office.

Advantages

- The rod works for up to 3 years
- There is no daily pill to take
- You can use it if you cannot take the hormone estrogen
- Your ability to have children may return quickly after removing the implant

Disadvantages

- Implant does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- May cause irregular and unpredictable bleeding
- Other side effects can include headache, acne, cramping and emotional changes

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- There can be side effects related to putting in the implant such as swelling, redness, pain, bruising, scarring, or infection
- There can be side effects related to removing the rod including a broken rod, or scar tissue making removal more difficult
- Rarely, it can be difficult or impossible to remove which may result in having to go to the operating room
- If you get pregnant, the chance of an ectopic pregnancy (a pregnancy not in your womb) is higher
- Ovarian cysts can occur
- May be less effective in women who are overweight or have liver problems –discuss this with your doctor
- Isotretinoin, antibiotics, and St. John's Wort may make the implant less effective

How soon does the implant work?

Discuss this with your healthcare provider.

Please make sure you can feel the implant rod under your skin after placement. If you cannot feel it, please do not start isotretinoin or have sexual intercourse until you talk to your healthcare provider.

Non-hormonal Intrauterine Device (Copper T IUD)

The Copper T IUD is a thin piece of plastic covered with the metal copper. It prevents pregnancy by slowing sperm down and keeping sperm from getting to the egg.

Who should not use the Copper T IUD?

Some of the reasons you should not use the Copper T IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus. You cannot use this IUD if you are allergic to copper or have Wilson's disease.

How do I use the Copper T IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The Copper T IUD can stay in place for up to 10 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Reference ID: 3956479

Advantages

- You can use it if you cannot take hormones.
- It is a good choice for long-term birth control (10 years).
- You may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps, heavy and longer menstrual periods.
- Your body may push out the IUD. This can happen without you knowing it. This occurs mostly during your menstrual period.
- You must check for the string to make sure it is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Tubal Sterilization (Tying Your Tubes)

Tubal sterilization (tying your tubes) is an operation that closes the tubes from the ovaries to the uterus so that the sperm cannot get through to the egg. Female sterilization may be accomplished using a variety of techniques. They are all considered to be very effective, virtually permanent methods of pregnancy prevention and, with the exception of hysteroscopic tubal sterilization, are immediately effective. Hysteroscopic tubal sterilizations are not effective immediately and require that a test be done in three months to confirm that the tubes are blocked. For the purposes of the iPLEDGE Program, hysteroscopic tubal sterilization is not considered an effective primary method of birth control unless the confirmation test has been performed.

Who should not have a tubal sterilization?

- You should not have a tubal sterilization if you ever want to get pregnant, at any time now or in the future.
- If you have already had a tubal sterilization, this is your primary form of birth control while taking isotretinoin. You must also choose either a secondary form of birth control or another primary form.
- If you are thinking about tubal sterilization, here is some information

Advantages

- It is very effective birth control.
- It works immediately after the surgery, with the exception of hysteroscopic tubal sterilization which requires that a test be done in three months to confirm that the tubes are blocked.

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Disadvantages

- Tubal sterilization does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If you want to have a child later, it is very difficult to re-open the tubes.
- It is surgery. You would need to have an operation.
- It increases the chance of ectopic pregnancy (pregnancy in the tubes) if sperm manage to get through the blocked tubes.

Partner's Vasectomy

A vasectomy is an operation that closes off the tubes that carry a man's sperm. The man's fluid should not have sperm in it after a vasectomy. If a man has sex before his doctor says his fluid has no sperm, the woman could get pregnant.

- If you have *only 1* partner *and* he has had a vasectomy, this can be your primary form of birth control while taking isotretinoin. You must also choose a second form of birth control. It is strongly recommended that you choose another primary form to give you very effective protection against getting pregnant.

If your partner is thinking about a vasectomy, here is some information about this very effective, but permanent, means of birth control.

Advantages

- It is very effective birth control.

Disadvantages

- A vasectomy does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If a male wants a child later, it is very difficult to open the tubes again.
- A vasectomy requires minor surgery.

Ask yourself:

- Is this my only sexual partner?

If you said no or if you are not sure, you cannot choose vasectomy as your primary form of birth control.

Reference ID: 3956479

SECONDARY FORMS OF BIRTH CONTROL

Secondary forms of birth control do not adequately protect against pregnancy if they are the only form used. However, they greatly increase your protection against getting pregnant if you use them along with a primary form every time you have sex. Effective secondary forms of birth control forms include barrier forms (male latex condoms, diaphragms, and cervical caps) and other forms (vaginal sponge). The diaphragm and cervical cap must always be used with a spermicide, and the male latex condom can be used with or without spermicide. The vaginal sponge contains spermicide. If a secondary form is your second form of birth control, you must use it every time you have sex with a male. The female condom is not an effective secondary form for the iPLEDGE Program.

Always use a spermicide with diaphragms and cervical caps.

Ask your doctor, gynecologist, or family doctor to show you how to use secondary forms. Be sure you know how to use them correctly.

Make sure you know exactly how to use these forms of birth control. Know what mistakes people make with secondary forms. These mistakes can get you pregnant.

Spermicides

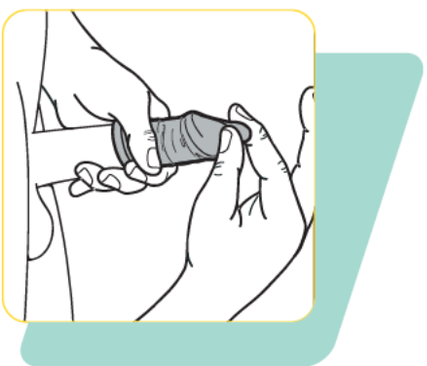
Spermicides come in several forms—creams, jellies, foams, and suppositories. You use spermicide 10 to 30 minutes before you have sex—each and every time—whenever the male comes in or near the female patient's vagina. Your dermatologist, gynecologist, family doctor, or birth control counselor can tell you how to use spermicides with your secondary barrier form.

Some people are allergic to spermicides. If you cannot use a spermicide, you must use 2 primary forms of birth control together, or a primary form with a male latex condom as your second form.

Male Latex Condom With or Without Spermicide

What is a male latex condom?

The male latex condom, also called a "rubber," is a thin cover put on the male's penis that traps sperm. You can use them with or without a spermicide .



How does my partner use it?

The male latex condom is unrolled on a male's erect penis as soon as he gets an erection. Waiting too long lets sperm leak out!

You can use a male latex condom with or without spermicide.

Reference ID: 3956479

A male latex condom is good for 1 time only. Do not let your partner try to use it more than once. Oils like petroleum jelly or baby oil can ruin a male latex condom. Safe lubricants include anything made with a water-based gel such as KY Jelly®.

Make sure the male latex condom stays on during sex. If it tears or comes off, call your doctor about emergency birth control.

Choosing a male latex condom as your secondary form

If you choose male latex condoms as a secondary form, your partner must be willing to use a male latex condom each and every time you have sex. Ask yourself:

- Does your sexual partner use a latex condom? Does he have a problem with using a latex condom each time you have sex?
- Does anyone ever force you to have sex if you do not want to?
- Have you and your partner ever forgotten to use latex condoms even when you had meant to?
- Have you ever had sex after drinking when you had not planned to?

  Alcohol and drugs can affect your judgment and decisions about having sex.

Male latex condoms may not be the best secondary form for you to choose if:

- Your partner does not want to use them
- You do not like to interrupt sex to let your partner put on a male latex condom
- You have had sex when you did not plan to and did not use birth control

You may want to choose a form you can control or one that you can insert before having sex.

Advantages

- Male latex condoms *do* protect against STIs (sexually transmitted infections) and HIV (AIDS).
- Male latex condoms are easy to buy, and no doctor's appointment or pelvic exam is needed.
- It is easy to tell when it breaks or slips.

Disadvantages

- Males and females can have a latex allergy.
- Male latex condoms can break or slip during sex.
- Many males do not like or want to use them. Your partner has to be committed to using male latex condoms. You are not in control of this birth control form.
- You must remember to use them every time.
- You must interrupt sex play to put on a male latex condom.

Reference ID: 3956479

How soon does a male latex condom work?

It works as soon as the male puts it on his erect penis.

Ask yourself:

- Will your partner actually use the latex condom?
- Did you talk with him about it?
- Did he agree?

1. Your partner says he is tired of using latex condoms and asks if he can skip it once in a while. Hormonal shots are your primary form of birth control. You should:

   A) Agree to let him just use a condom every other time you have sex

   B) Tell him to use latex condoms until you get a diaphragm to use

   C) Tell him that you will not have sex with him unless he uses a latex condom

   D) Not worry because you have not gotten pregnant yet

Answer key: page 38

Diaphragm And Spermicide

What is a diaphragm?

The diaphragm is a shallow latex cup edged with a flexible ring. It covers your cervix and keeps sperm from getting into your uterus. Your gynecologist or family doctor can fit you with one.

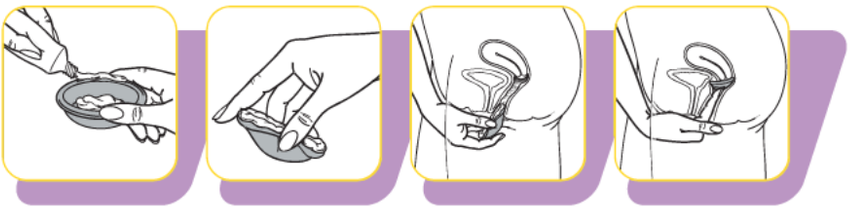
Who should not use the diaphragm?

You should not use a diaphragm if you have an allergy to latex or silicone, difficulty putting the diaphragm in, weak vaginal muscles, a history of bladder infections or toxic shock, or had a recent abortion.

Reference ID: 3956479

How do I use a diaphragm?

You bend the flexible ring and insert the diaphragm into your vagina. The back rim rests below and behind the cervix. The front rim is tucked behind your pubic bone. Before you insert it, you put spermicide in the center of the cup and around the ring.



You can put your diaphragm into the vagina up to 6 hours before sex. You have to leave it in place for at least 6 hours after you have sex. You must put spermicide in the vagina if you have sex again during this time. You should not leave it in for more than 24 hours at a time.

Choosing a diaphragm as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using diaphragms. If you are in one of these 2 groups, talk with your dermatologist, gynecologist, family doctor, or birth control counselor about whether the diaphragm is right for you.

Have you ever used a diaphragm? What do you like or dislike about the diaphragm?

- Do you find it easy to put it in?
- Have you been using spermicide with the diaphragm?
- Do you find it easy to remember to use it?
- Have you had your diaphragm checked by your gynecologist in the last 2 years to see if it still fits? You must have your diaphragm checked every 2 years, after a gain or loss of 10 pounds, OR after childbirth or an abortion.

If you answered yes to these questions, the diaphragm may be a good secondary form for you.

If you answered no to any of these questions, you should think about another secondary form.

Advantages

- You can easily carry a diaphragm with you and control its use.
- It is immediately effective.
- There are no hormones.
- You do not have to interrupt sex play—it can be inserted before sex.
- You can use it during your menstrual period.

Reference ID: 3956479

Disadvantages

- A diaphragm does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it hard to insert.
- You must put spermicide in your vagina if you have sex again.
- It can get pushed out of place during sex.
- It requires a prescription and pelvic exam. A diaphragm lasts about 1 to 2 years.
- You must check it for holes and tears and clean it after sex.

How soon does a diaphragm work?

It works as soon as spermicide is applied and you put it in correctly.

Cervical Cap And Spermicide

What is the cervical cap?

The cervical cap is a small latex or rubber cup. You use it with spermicide. It covers your cervix so that sperm cannot get in your uterus. It must fit perfectly to work. Your gynecologist or family doctor can fit you for one.

Who should not use a cervical cap?

You should not use a cervical cap if you have an allergy to latex or rubber, a history of pelvic infections, abnormal Pap tests, or Toxic Shock Syndrome (TSS).

How do I use a cervical cap?

The cap is filled one-third full with spermicide. You squeeze it as you put it in your vagina. You press it onto the cervix to cover it completely. You can put the cap in the vagina right before sex, but it stays better if you put it in place 30 minutes before sex. You have to leave it in place for at least 6 hours after you have sex. You can leave in place up to 48 hours.

The cervical cap is made of latex. Never use it with an oil-based lubricant like petroleum jelly. This will destroy the cap.

Reference ID: 3956479

What is the difference between a diaphragm and a cervical cap?

The cervical cap is a little harder to learn how to use. With a cervical cap, there is no need to insert extra spermicide if you have sex again. You can also leave the cap in place for a longer time—48 hours instead of 24 hours. You cannot use the cervical cap if there is any vaginal bleeding, such as during your menstrual period.

Choosing the cervical cap as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using the cervical cap. If you are in one of these 2 groups, talk with your gynecologist or family doctor about whether the cervical cap is right for you.

Have you ever used a cervical cap? What do you like or dislike about it?

- Do you find it easy to put in?
- Have you been using spermicide with the cervical cap?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the cervical cap may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Advantages

- You can easily carry a cervical cap with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance.

Disadvantages

- A cervical cap does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it harder to insert than a diaphragm.
- You cannot use it during your menstrual period.
- You need a prescription and a pelvic examination to fit a cervical cap.
- A cap lasts about 1 year.
- You must check it for holes and tears and clean it after sex.

Reference ID: 3956479

Vaginal Sponge

What is the vaginal sponge?

The vaginal sponge is a soft foam disc or pillow containing 1 gram of the spermicide nonoxynol-9. Inserting the sponge puts spermicide in your vagina and keeps it there during sex. You insert it in the vagina so it sits over your cervix. It has a string loop attached for easy removal.

Who should not use a vaginal sponge?

Female patients who are allergic to the spermicide nonoxynol-9 should not use the vaginal sponge.

How do I use the vaginal sponge?

First, wash your hands. Wet the sponge thoroughly with clean tap water. Squeeze the sponge gently several times until it is foamy. This releases the spermicide. Pinch the sides of the sponge together. Be sure the string loop is on the underside of the sponge. Squat or sit down, bend your wrist, and push the sponge gently up into your vagina as far as it will go. Check the position of the sponge to make sure the sponge covers your cervix.

How do I take the sponge out?

Wait at least 6 hours after your last sexual activity before taking the sponge out. You can leave it in place for up to 30 hours. You do not need more spermicide if you have sex more than once during that time. To take the sponge out, you need to catch the string loop and gently pull on it.

Choosing the vaginal sponge as your secondary form

Have you ever used a vaginal sponge? What do you like or dislike about it?

- Do you find it easy to put in? Easy to take out?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the vaginal sponge may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Reference ID: 3956479

Advantages

- You can easily carry a vaginal sponge with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance and is effective for up to 30 hours.
- No fitting is needed; you can buy it over the counter.
- It is comfortable and easy to use.

Disadvantages

- The vaginal sponge does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- It is not as effective in female patients who have had children.

EMERGENCY BIRTH CONTROL (Emergency Contraception)

Emergency birth control is also called "after sex" or "morning after" birth control. It can prevent pregnancy after sex without adequate protection. Emergency birth control prevents release of the egg, joining of the sperm and the egg, or implanting of the egg in the uterus. Emergency birth control is only for a female patient who is sure she is not already pregnant.

There are 2 forms of emergency birth control:

1. Emergency Contraceptive Pills (ECPs)—some must be used within 3 days, others must be used within 5 days of having sex without adequate protection. The sooner you take ECP, the more likely it is to work. It is best if ECP begins within 12 hours after you have sex without adequate protection. The pills may give you severe nausea. Ask your doctor for something to help with the nausea if you need this treatment. ECP does not take the place of your usual birth control, nor does it continue to prevent pregnancy during the rest of your menstrual cycle.

2. Putting in an IUD—used within 5 days. You need to have the IUD inserted within 5 days of having sex without adequate protection.

When would I need emergency birth control?

Call your doctor or gynecologist about emergency birth control if you had sex without adequate protection, such as:

- You forgot to take 2 or more birth control pills and had sex.
- You had sex without using a second form of birth control.
- You were late for your birth control hormonal shot and had sex.
- Your partner's condom broke or slipped off.
- Your diaphragm or cervical cap slipped out of place or ripped during sex.

Reference ID: 3956479

Emergency birth control is meant only for emergencies. It does NOT take the place of your usual 2 forms of birth control and it will not protect against sexually transmitted infections (STIs). Emergency birth control is not to be used instead of regular birth control and it does not work if you are already pregnant.

Where can I get emergency birth control?

You can get emergency birth control from:

- Private doctors or nurse practitioners
- Planned Parenthood
- Women's health centers
- Many hospital emergency rooms (unless they are owned by organizations opposing birth control)
- Available over-the-counter

Whom should I call if I cannot find emergency birth control?

Call the private toll-free Emergency Contraception Hotline at 1-888-NOT-2-LATE (1- 888-668-2528). They will ask for your city or ZIP code to help you find emergency birth control near you.

Ask yourself:

1. The right way to use emergency birth control is:
   - A) As a second form of birth control
   - B) If you find a tear in your cervical cap after sex
   - C)If you missed several birth control pills and then have sex
   - D) Only after a positive pregnancy test

Answer key: page 38.

REASONS FEMALE PATIENTS GET PREGNANT

There are many reasons female patients get pregnant when they do not want to. You can avoid most of these.

- They did not avoid sex with a male when they were not using birth control.
- They used a birth control form that did not work very well.
- They did not use birth control all the time and every time they had sex.
- They did not use their birth control the right way.
- They had sex with a male partner when they were not expecting to.
- Their birth control form failed.

For most of the reasons, you can make a choice not to make the same mistake. It is very important that you are careful about birth control. Use your birth control as the iPLEDGE Program requires. Do not make mistakes that can lead to unexpected pregnancy.

Reference ID: 3956479

SEPARATING THE MYTHS FROM THE FACTS

Myths are ideas that many people believe are true, but they are not true. You need to know the facts about sex, birth control, and pregnancy to protect yourself.

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
You cannot get pregnant the first time you have sex.	You can get pregnant **any** time you have sex.
You cannot get pregnant if you "do it" standing up.	You can get pregnant in any position.
You will not get pregnant if you do not have an orgasm (come).	You can get pregnant any time you have sex regardless of whether or not you have an orgasm.
Douching keeps you from getting pregnant.	Douching does **not** prevent pregnancy.
You do not have to use something every time.	You should use birth control every time you have sex.
You will not get pregnant if it is the "safe time" of the month.	There is no safe time, even for female patients who are regular with their menstrual periods. Your body can change and you could get pregnant.
You will not get pregnant if he pulls out before he comes.	Even if he pulls out, he may leak sperm before he comes and you can get pregnant.
It is safe for me to have sex any time, unless I feel PMS changes or pain near my ovaries.	You can get pregnant any time you have sex, not just when you think you are ovulating (releasing an egg).
You cannot get pregnant if you have not had a menstrual period yet.	Your ovaries release an egg (ovulation) before your first menstrual period. You can get pregnant even the very first time this happens, if you have been having sex.
You cannot get pregnant if you have sex underwater.	You can get pregnant **anywhere** you have sex.

Reference ID: 3956479

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
My partner says he is sterile (has no sperm) because he had mumps. He never got anyone else pregnant, so I will not get pregnant.	Mumps rarely causes sterility (no sperm). You can get pregnant if you have sex with a man who has had mumps.
You cannot get pregnant if you miss only 1 birth control pill.	Birth control pills work best when you take them as prescribed. You can get pregnant if you miss even one pill, especially at the beginning of your pill cycle
Sexually active means you have to move during sex. If I do not move, I cannot get pregnant.	You can get pregnant any time you have sex, whether you move or lie still.
I am going through menopause and only get my menstrual period every couple of months.	You can get pregnant until you have missed your menstrual period for 1 year—12 months in a row.

You may have heard or read about something that is not listed here that you think might keep you from getting pregnant. Be sure to ask your dermatologist, gynecologist, or family doctor about any form that you cannot find in this book that you think, or have heard, will keep you from getting pregnant. You can only use the effective forms of birth control for the iPLEDGE Program.

SEX, ALCOHOL, AND DRUGS

You have seen this message many times before. Alcohol and drugs can make you unable to use good judgment. While you are taking isotretinoin and for 1 month after your last dose, you need to be able to remember to use 2 effective forms of birth control together each and every time you have sex with a male.

Do not let drugs or alcohol keep you from using your secondary form when you have sex. Use it the right way. You need to be in control of yourself so:

- You use your secondary form, OR you get your partner to use a male latex condom with or without spermicide
- You use a vaginal sponge, or a diaphragm or a cervical cap with spermicide

Reference ID: 3956479

RECOGNIZING PREGNANCY

If you think you might be pregnant, stop isotretinoin and call your doctor right away. Here are some signs that you might be pregnant:

- You miss your menstrual period.
- You have nausea first thing in the morning.
- Your breasts feel really tender, like at the beginning of a menstrual period.
- The area around your nipples may look darker.
- You feel really tired and want to sleep.
- You feel you have to go to the bathroom a lot.
- You may have spotting of blood at the time of your menstrual period, but no real bleeding.

Ectopic (Tubal) Pregnancy

Sometimes a baby starts to grow outside the uterus. This is a serious problem. Call your doctor right away, if you have these signs:

- Sudden pain or severe cramping in your lower abdomen
- Bleeding or spotting with abdominal pain after you miss a menstrual period
- Fainting or dizziness lasting more than a few seconds

Pregnancy Testing

If you have any questions about whether you might be pregnant, talk with your doctor.

Reference ID: 3956479

NOTES:

NOTES:

Birth Control Information

You can get information about birth control 24 hours a day, 7 days a week on the telephone. Call the toll-free number **1-866-495-0654** to learn about these subjects:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

This telephone line is for education only. It does not take the place of talking with your doctor. He or she is the best source of information for you.

Answer Key To Birth Control Questions

Page 8:
- 1. B
- 2. A and D

Page 11:
- 1. B
- 2. B and C
- 3. A

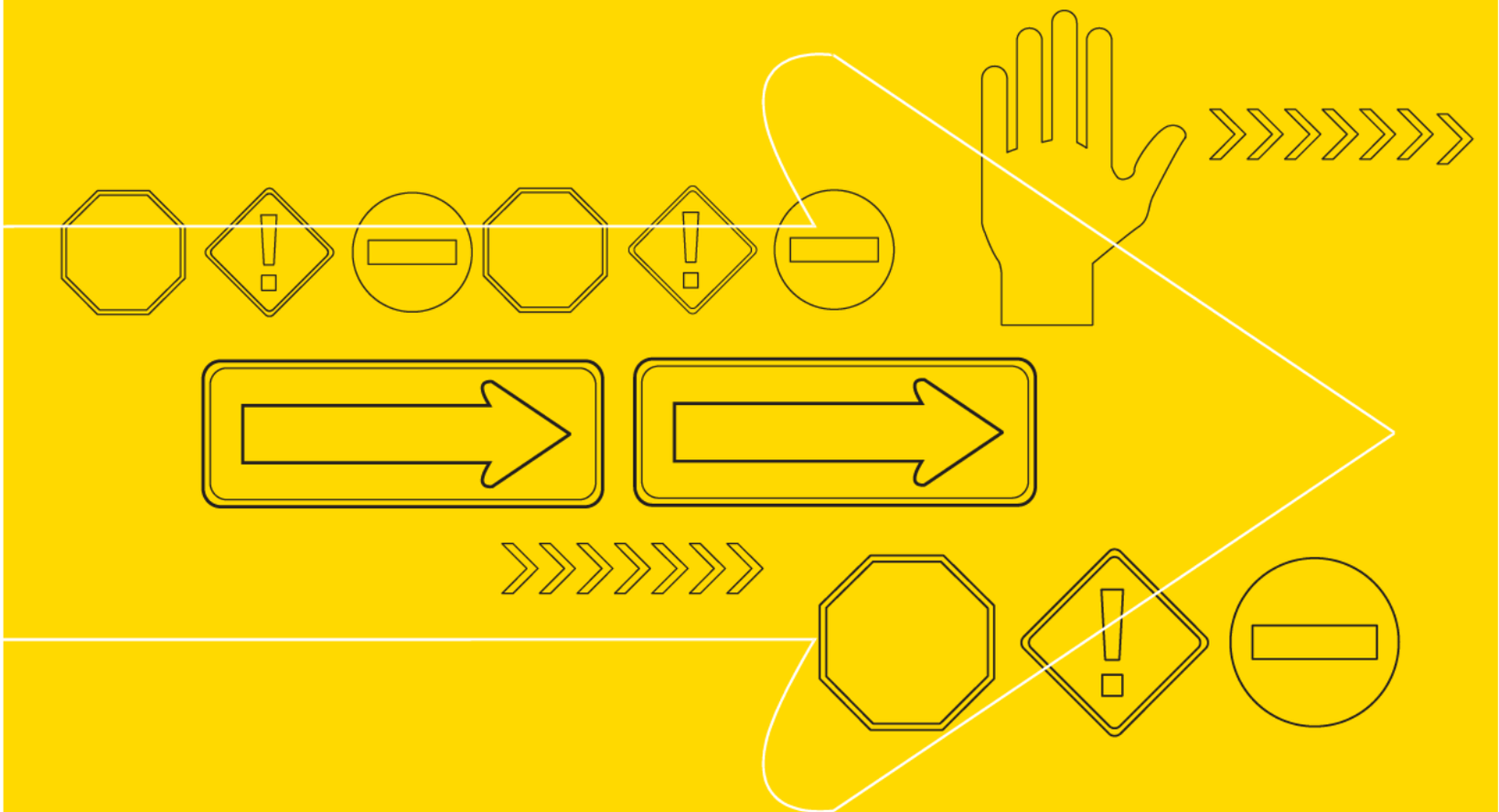
Page 14:
- 1. B
- 2. C

Page 20:
- 1. A and D

Page 26:
- 1. B and C

Page 32:
- 1. B and C

Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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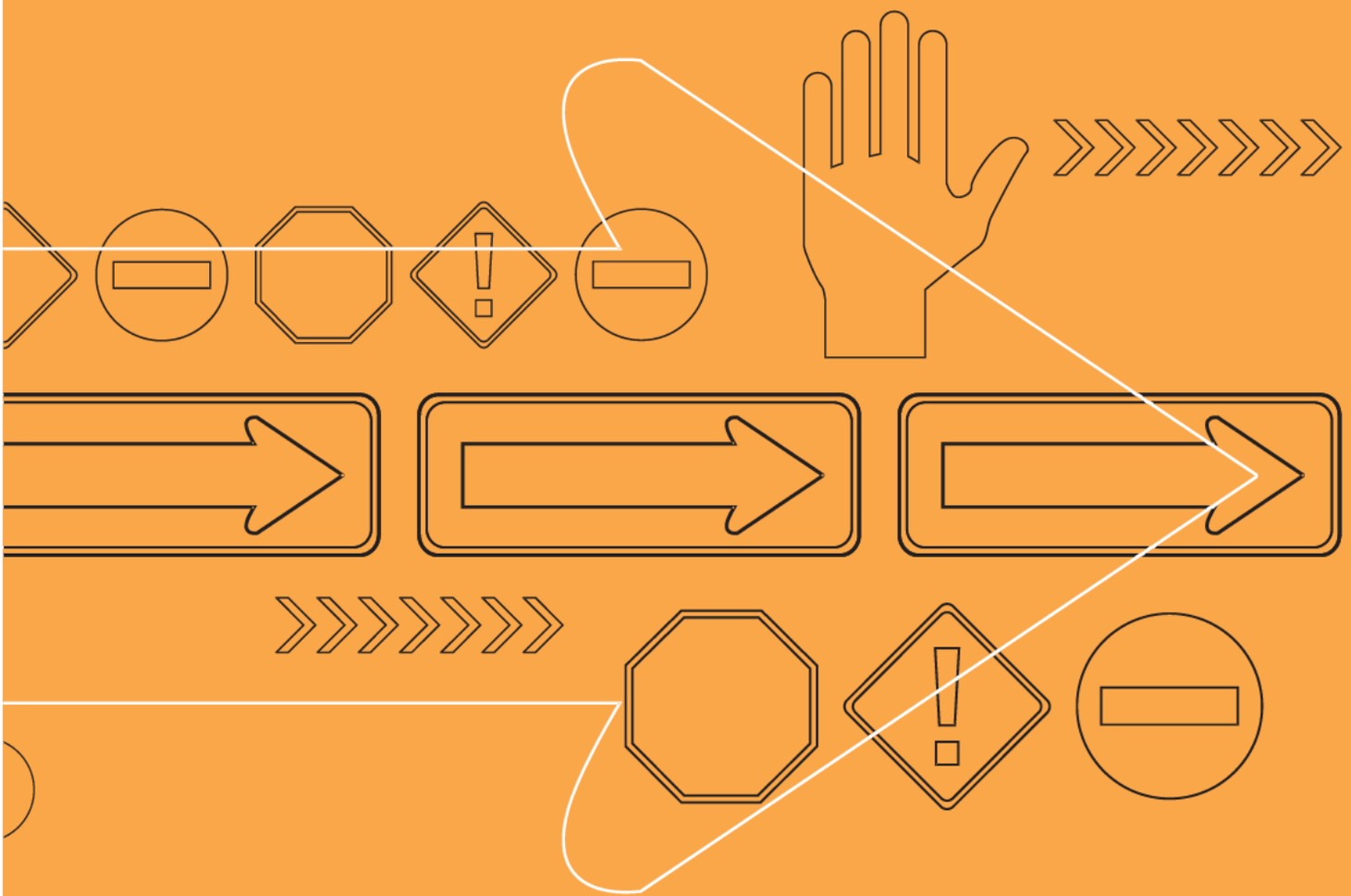
Reference ID: 3956479

Contraception Referral Form And Contraception Counseling Guide



Referral form
for contraception
counseling and guide
for counselors on
effective forms
of contraception

Reference ID: 3956479

Most Recent Modification: July 2016

The iPLEDGE Program

Contraception Referral Form And Contraception Counseling Guide

Referral form for contraception counseling and guide for counselors to effective forms of contraception

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Reference ID: 3956479

Contraception Referral Form And Contraception Counseling Guide

TABLE OF CONTENTS

Contraception counseling for isotretinoin patients 4

Counseling goals 5

Contraception requirements 6

Unacceptable forms of contraception 8

Emergency contraception 9

Abstinence 9

Reporting a pregnancy 10

About This Referral Form

The Isotretinoin Contraception Referral Form, brought in to you by this patient, has been filled out in part by the prescriber. Please fill out the rest of the form at the conclusion of your counseling session and fax or mail the copy back to the prescriber, keeping a copy for your own records.

On the back of the referral form is a reimbursement form for contraceptive counseling services. The iPLEDGE Program provides reimbursement for 1 contraception counseling session for patients who have been prescribed isotretinoin. Please complete the form and fax it to 1-866-495-0660.

Reference ID: 3956479

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Committed to Pregnancy Prevention

iPLEDGE–Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

ISOTRETINOIN CONTRACEPTION REFERRAL FORM

Prescriber: Complete for Patients Being Referred for Contraception Counseling

Patient_____, iPLEDGE Program ID#_____
is considering treatment with isotretinoin. I am referring her for counseling to help her choose her 2 forms of contraception before she receives her first prescription.

Please complete the Record of Contraception Counseling below and return this form to my office, via fax or mail.

She had a negative (serum/urine) pregnancy test on _____

Please review this *Contraception Counseling Guide* for details on the iPLEDGE Program contraception requirements.

Isotretinoin Prescriber's Name_____

Address _____

Telephone _____-_____-_____ Fax _____-_____-_____

Isotretinoin Prescriber's Signature _____

Date _____

RECORD OF CONTRACEPTION COUNSELING

Contraception Counselor: Complete Form and Fax or Mail Back to Isotretinoin Prescriber

I have provided the following for your patient _____

- ❑ Comprehensive contraception counseling
- ❑ Information about emergency contraception

The patient has:

- ❑ Not yet decided upon the forms of contraception she will use
- ❑ Chosen 2 forms of contraception
- ❑ Decided to abstain from any sexual contact with a male and is not planning to use 2 forms of contraception. I informed her that abstinence without using contraception is not recommended for the iPLEDGE Program for sexually active women.

Primary Form _____

Secondary or Second Primary Form_____

I have prescribed the selected contraception.

❑ Yes ❑ No (Please comment below)

I believe that this patient is fully committed to complying with the contraceptive requirements of the iPLEDGE Program.

❑ Yes ❑ No (Please comment below)

_____

Name_____

Address _____

Telephone _____

Specialty (circle one): OB-GYN Fam Prac IM RN LPN Other_____

Contraception Counselor's Signature _____

Date _____

Prescriber Copy-White **Contraception Counselor Copy-Yellow** **Patient Copy-Pink**

Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

www.ipledgeprogram.com | 1-866-495-0654

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FAXABLE REIMBURSEMENT FORM

The Following Restrictions Apply:

Only consulting clinicians who provide initial pregnancy prevention counseling are eligible for reimbursement for such counseling. Other services provided during this visit are not eligible for reimbursement. The physician prescribing isotretinoin, or any other person working under the direct supervision of said physician, is not eligible for this reimbursement provision. The reimbursement fee is up to $150.00, which has been determined to be an average, usual, and customary reimbursement for service of this type. Information will be used only for reimbursement; the isotretinoin manufacturers will not use it for any other purpose.

Reimbursement For Pregnancy Prevention Counseling

To receive reimbursement for providing pregnancy prevention counseling to an isotretinoin patient, please answer the following questions, and sign, date, and send the completed form via fax to: 1-866-495-0660.

Contraception Counselor Name_____

Payee Name (if different than Contraceptive Counselor) _____

Office Telephone Number _____-_____-_____ Tax ID Number

Payee Address _____

City_____ State _____ ZIP _____

Name of Referring Physician _____

Office Telephone Number_____-_____-_____-_____

City_____ State _____ ZIP _____

Patient's Name _____

Patient's iPLEDGE Program ID Number _____

- ❑ I have provided pregnancy prevention counseling to this patient. I have mailed or faxed the record of pregnancy prevention counseling (on reverse side) to the isotretinoin prescriber.
- ❑ I am not the prescribing physician of isotretinoin to the patient referenced above, nor am I employed by said prescribing physician.
- ❑ I have not, and will not, bill or submit for reimbursement either directly or indirectly, under Medicaid, Medicare, or similar federal or state healthcare programs, or under any private insurance, HMO, or other healthcare benefit program for the pregnancy prevention counseling services described above.
- ❑ I attest that all of the above information is accurate and understand that I must check each box above to receive reimbursement.
- ❑ I have included a signed W-9 Form, or already have a W-9 form on file for payment from the iPLEDGE Program. A blank W-9 form and instructions for completion can be found at www.irs.gov

Signature _____ Date _____

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10613-7 NOV07

Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

www.ipledgeprogram.com | 1-866-495-0654

Reference ID: 3956479

CONTRACEPTION COUNSELING FOR ISOTRETINOIN PATIENTS

Isotretinoin is used to treat severe recalcitrant nodular acne; however, it is also a known human teratogen. Over one third of all babies exposed to isotretinoin *in utero* and carried to term have major birth defects.[1,2] The public health goal for isotretinoin is to eliminate fetal exposure by ensuring that no female starts isotretinoin therapy if pregnant and no female on isotretinoin therapy becomes pregnant. The US Food and Drug Administration has approved the iPLEDGE Program, an enhanced pregnancy risk management program for isotretinoin, to help achieve that end.

The contraception that a patient selects can have a dramatic effect on her chance of becoming pregnant. A patient using isotretinoin needs to select forms with low failure rates that she and/or her partner will use correctly each time they have intercourse.

Your Role

This patient is being referred to you because she has asked for counseling to help her comply with the contraception requirements of the iPLEDGE Program.

The patient must select and commit to using 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. She must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy.

It is strongly recommended that a patient use a primary form of contraception and is committed to using a second form as well, even if she says she will be abstinent for the entire required period. Isotretinoin is not recommended for sexually active females of reproductive potential whom you believe will not be able to maintain abstinence or will not use contraception, as the program requires.

Please read this iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide completely before you begin your counseling session. It provides a pregnancy risk management context through which contraception choices for female patients taking isotretinoin can be viewed. It does not contain detailed information on the various forms of contraception.

The iPLEDGE Program Birth Control Workbook, which is for patients, contains more information on effective primary and secondary forms of contraception. It is not complete information on any of the forms, and the patient is encouraged to ask questions about specific forms or issues. The workbook has questions on such issues as medication adherence and lifestyle choices for the patient to think about in choosing contraception. Please review her responses with her.

Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Reference ID: 3956479

COUNSELING GOALS

Ensure That The Patient:

- Understands the risk of having a child with significant birth defects from exposure to isotretinoin.
- Understands the need for using 2 forms of contraception together consistently and correctly and knows when to contact her prescriber for emergency contraception.
- Chooses the forms of contraception that will work best for her, that will provide her with the lowest practical failure rate, and that she and her partner will actually use. Adherence impacts the failure rate of hormonal combination oral contraceptives more strongly than other primary forms. (Please see "Hormonal Combination Oral Contraceptives As A Primary Form" on page 6.)
- Commits fully to not becoming pregnant and to using 2 forms of contraception simultaneously, consistently, and correctly. In previous isotretinoin risk management programs, patients understood the need for 2 forms of contraception; however, they did not comply, despite adequate information about the risk to the fetus. If, after counseling, the patient recognizes she will not be able to commit fully, encourage her to not take isotretinoin or do not prescribe.
- Is able and willing to maintain abstinence, if that is her choice after counseling. If a patient who has ever been sexually active chooses abstinence, and you believe that she will not be able to maintain abstinence and will not use contraception, encourage her to not take isotretinoin.

Counseling younger teens

For younger teens, it is important to stress the following aspects of contraception for the iPLEDGE Program during counseling:

- The birth control forms that are effective as primary and secondary forms.
- Why it is important to use 2 forms of birth control. Younger teens may need more emphasis on this point to fully understand it and comply.
- Emergency contraception. Younger teens may need more explanation from you about the need to take immediate action if they had unprotected sex.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

CONTRACEPTION REQUIREMENTS

Using 2 Forms Of Contraception Provides More Protection

Use of 2 forms of contraception (at least one of which is a primary form) simultaneously substantially reduces the chances that a female will become pregnant over the risk of pregnancy with either form alone.

In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin.[3] Because of this possibility and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE Program requires the additional protection of a second form of contraception.

Selecting An Effective Primary Form Of Contraception

Table 1 on the next page lists, by typical use failure rate, the primary forms of contraception acceptable in the iPLEDGE Program. The single most important decision in contraception for the iPLEDGE Program is selecting a primary form with a very low failure rate that the patient can and will use as perfectly as possible. Other important factors to consider in selecting a primary form include side effects, contraindications, and willingness and ability to use it perfectly. All of these factors influence compliance and the chance of unwanted pregnancy.

Hormonal Combination Oral Contraceptives As A Primary Form

If the patient is currently taking or planning to take oral contraceptives, review that section in *The iPLEDGE Program Birth Control Workbook* with her. Her answers to questions on consistency and medication adherence will provide insight into potential issues with iPLEDGE Program adherence.

Other contraception not requiring daily choices may be a better choice for a patient who does not take oral contraceptives perfectly. For example, if such a patient chooses an IUD, she reduces her chances of becoming pregnant by up to approximately 90%.[3] It is critical that such a patient choose a form other than oral contraceptive agents.

Table 1: Primary Forms Of Contraception By Typical Use Failure Rate

	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	**Perfect Use**	**Typical Use**
Hormonal Implantable	0.05%	0.05%
Partner's Vasectomy	0.10%	0.15%
Hormonal IUD (LNg20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A)[b]	0.60%	0.80%
Hormonal Injectable (single)	0.30%	3.00%
Hormonal Transdermal Patch	0.30%	8.00%
Hormonal Vaginal Ring	0.30%	8.00%
Hormonal Combination Oral Contraceptives[b]	0.30%	8.00%

a Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al, eds *Contraceptive Technology.* Nineteenth Revised Edition, New York, NY: Ardent Media 2007

b The IUD Progesterone T and progestin-only "mini-pills" are not acceptable primary forms for the iPLEDGE program (See "Unacceptable Forms Of Contraception" on page 8)

Selecting An Effective Secondary Form Of Contraception

Table 2 lists the acceptable secondary forms of contraception in the iPLEDGE Program. There are 2 forms of secondary contraception: barrier and other. Barrier forms include the diaphragm and cervical cap (both of which must be used with spermicide) and the male latex condom (which can be used with or without spermicide). The other form is the vaginal sponge, which contains spermicide. The most important issue for a secondary form is whether it will be used each time the patient has intercourse (i.e., will it be in place when the first form fails). Failure rate with perfect use is of secondary importance.

Help the patient select a secondary form that she and/or her partner can fully commit to using correctly each time they have intercourse. If it is apparent that more than 1 of the forms would be equally suited, select the form with the lower or lowest perfect use failure rate, as this will reduce the overall likelihood of becoming pregnant.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Table 2: Secondary Forms Of Contraception Listed By Typical Use Failure Rate		
	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	**Perfect Use**	**Typical Use**
Barrier Forms		
Male Latex Condom[b]	2%	15%
Diaphragm[*]	6%	16%
Cervical Cap[d,*]	9%	20%
Other Forms		
Vaginal Sponge[c]	9%	16%

a Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al, eds *Contraceptive Technology* 19th Revised Edition, New York, NY: Ardent Media, 2007

b Female condoms are not acceptable for the iPLEDGE program (See "Unacceptable Forms Of Contraception" below) Failure rate for Male Latex Condom is for use without spermicide

c Failure rate for nulliparous women; rate is approximately double for parous women

d Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al,eds *Contraceptive Technology*. 17th Edition, New York, NY: Irvington Publishers 1998

* Failure rates for Diaphragm and Cervical Cap include the use of spermicide

UNACCEPTABLE FORMS OF CONTRACEPTION

The following forms of contraception are not acceptable for the iPLEDGE Program:

- Progesterone-only "mini-pills"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix[‡]

Patients currently using these forms of contraception must switch to effective forms of contraception. They must use 2 effective forms together (at least one of which must be a primary form) consistently and correctly for at least 1 month and have a negative pregnancy test before beginning isotretinoin.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479

EMERGENCY CONTRACEPTION

Review this section in *The iPLEDGE Program Birth Control Workbook* with the patient. She should know when to call her prescriber for possible emergency contraception. She should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms she selected.

ABSTINENCE

For this program, all females of reproductive potential must fully commit to pregnancy prevention. Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE Program who are or have been sexually active. Abstinence may be appropriate when it is a lifestyle choice, such as religious practice, and not just a social circumstance, such as not having a current partner. If, after counseling, a sexually active patient chooses abstinence without contraception, she must understand that isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program.

REFERENCES

1 Lammer EJ, Chen DT, Hoar RM, et al Retinoic acid embryopthy *N Engl J Med* 1985;313:837-841
2 Gideon K, Avner M, Shear N Generic isotretinoin: a new risk for unborn children *CMAJ* 2004;170:1567-1568
3 Isotretinoin Prescribing Information, 2005

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479

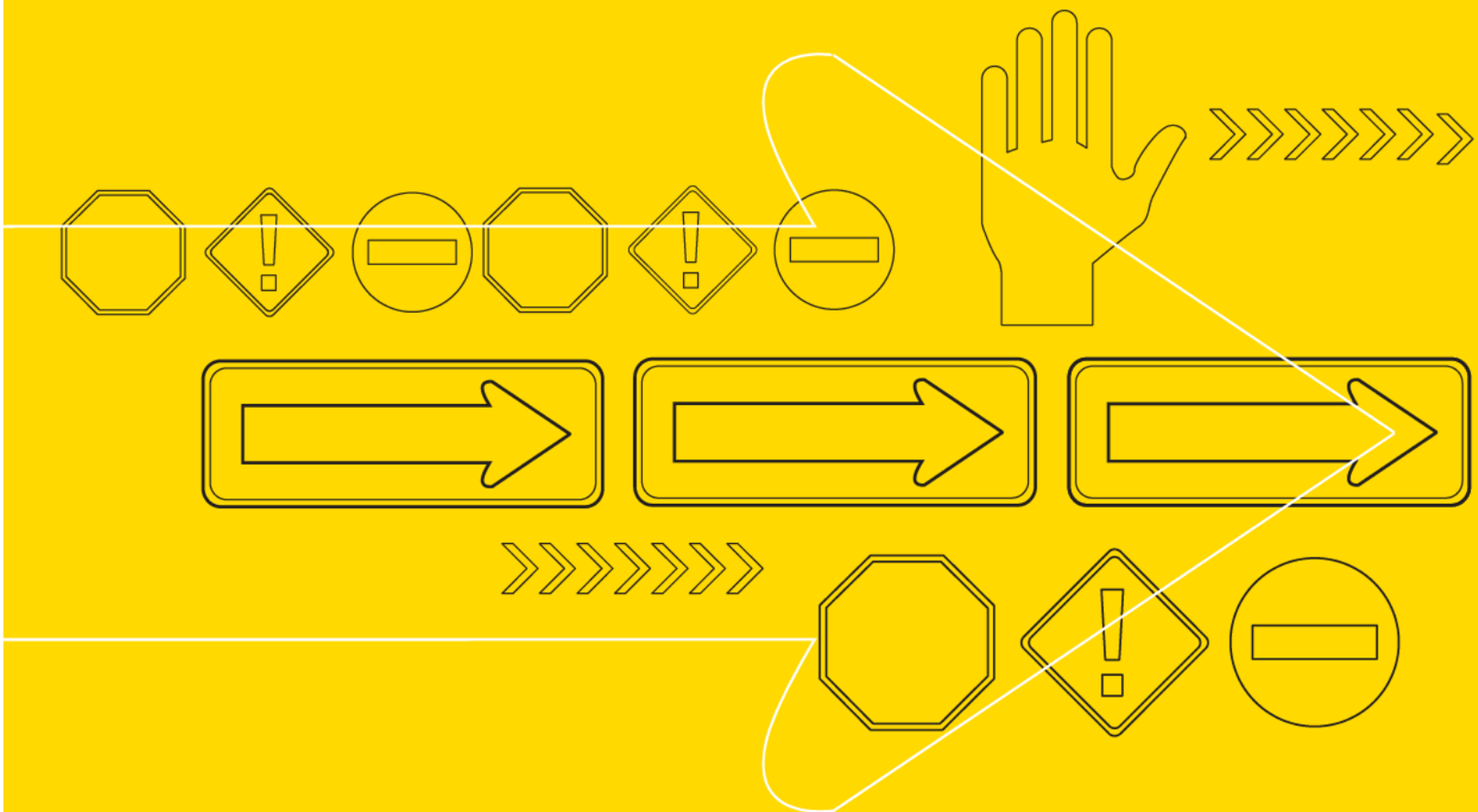
Reporting a Pregnancy

If you become aware of a pregnancy in a patient taking isotretinoin, please report the pregnancy to the iPLEDGE Program by calling **1-866-495-0654** and choosing the option to "Report a Pregnancy."

Please also remind any patient who is pregnant to contact the doctor who prescribed her isotretinoin.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™

Committed to Pregnancy Prevention

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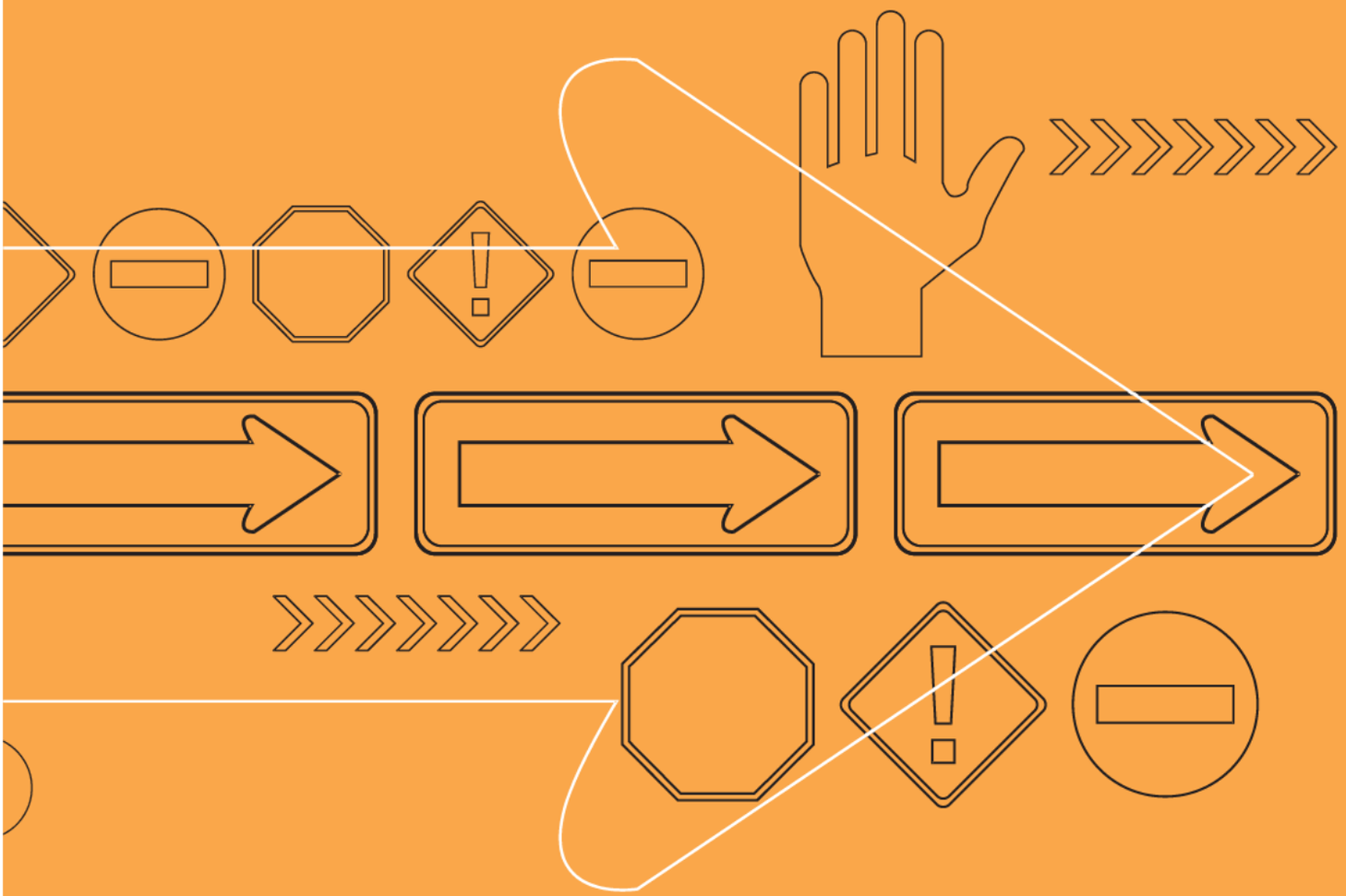
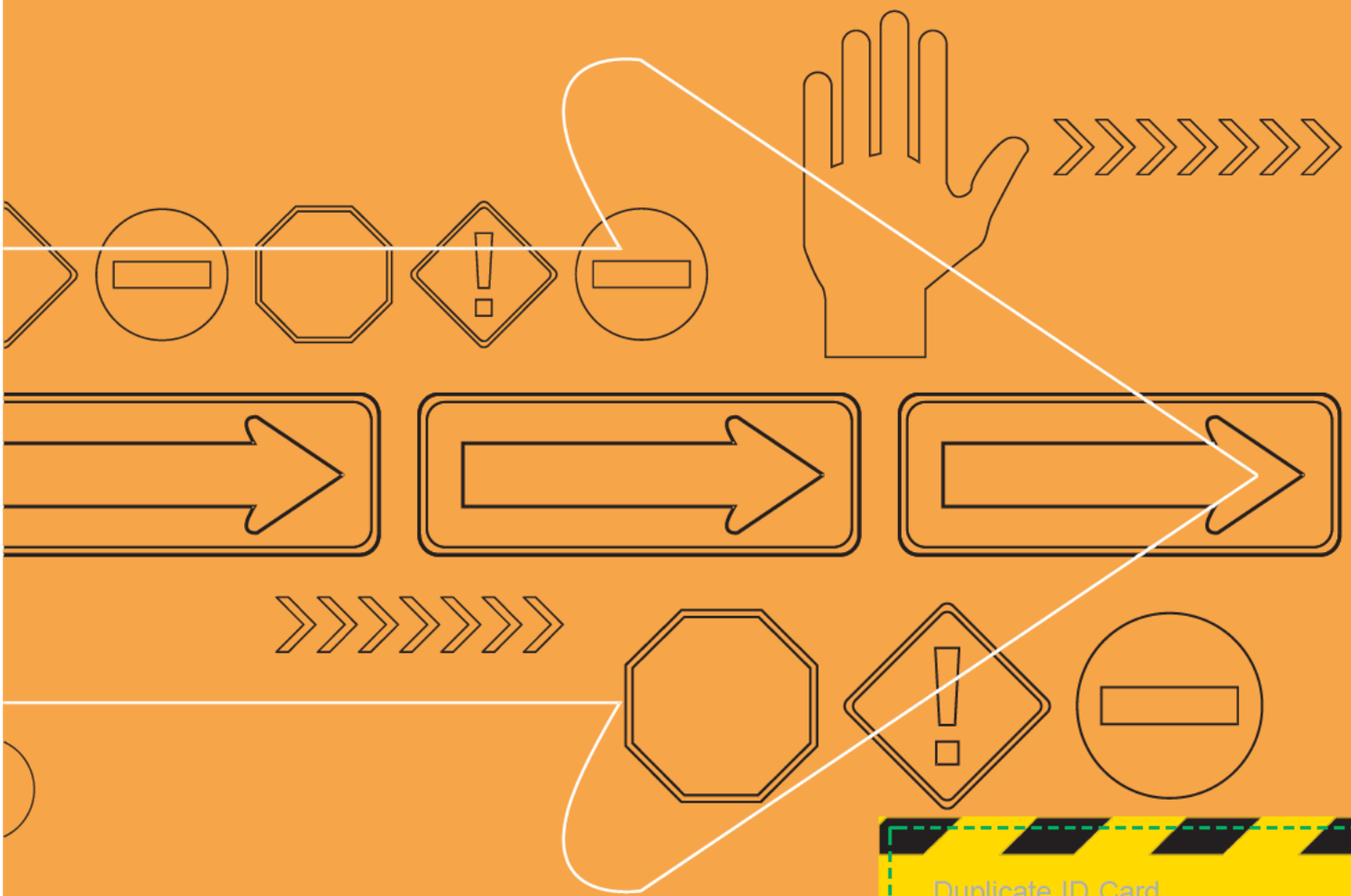
Reference ID: 3956479

Patient Identification Card



- The card you need to take with you to doctor visits and to the pharmacy while on isotretinoin

Reference ID: 3956479



Peel off sticker for patient's file

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your 7-day window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your 7-day window
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See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

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- Take this card and your prescription to the pharmacy within your 7-day window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you are pregnant.
Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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Stop isotretinoin and call your doctor right away if you are pregnant.
Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
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- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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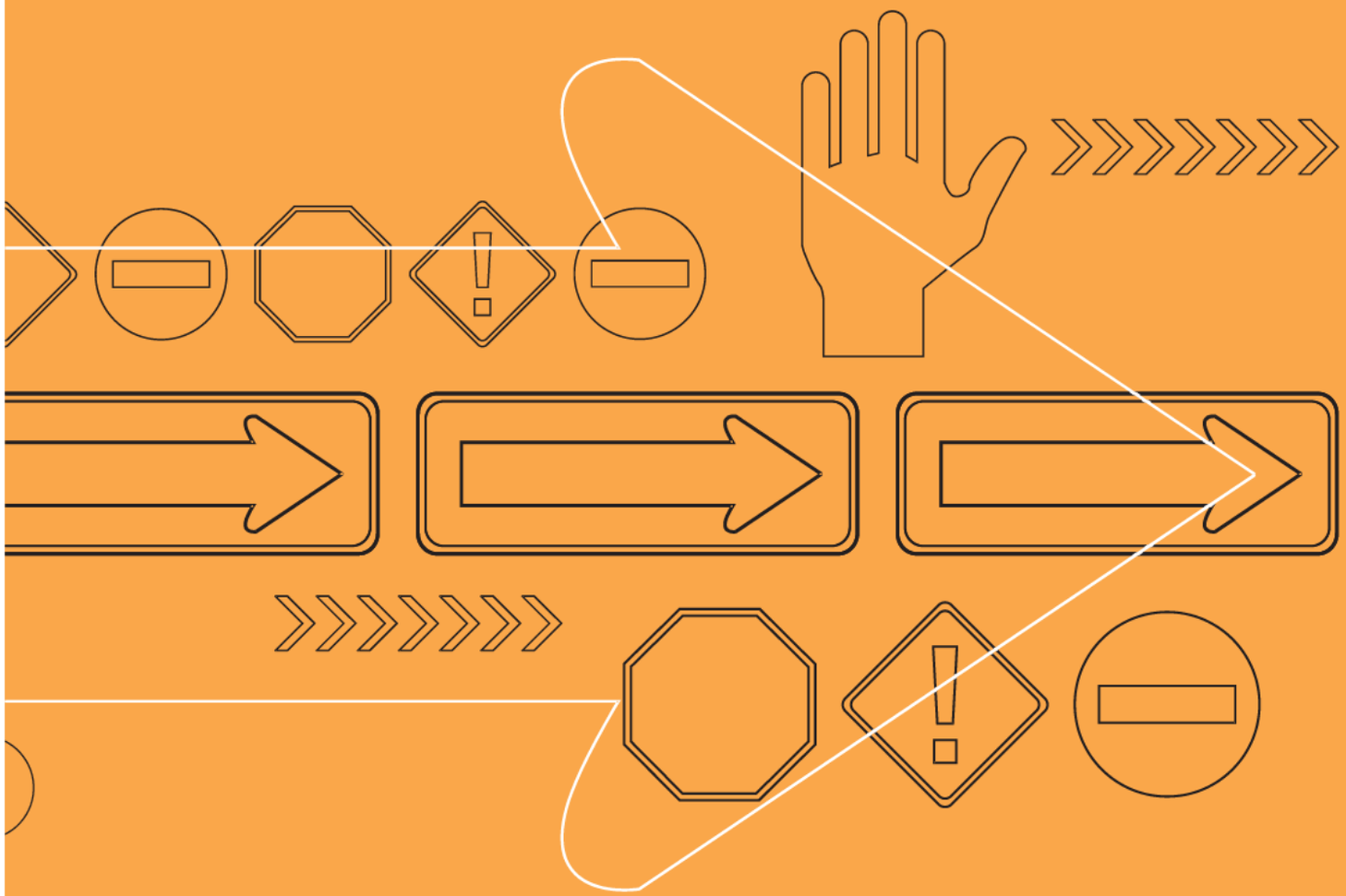

> Important forms you must sign before you begin taking isotretinoin

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P.O. Box 29094
Phoenix, AZ 85038

Patient Information/Informed Consent (for all patients):

To be completed by patient (and parent or guardian if patient is under age 18) and signed by the doctor.

Read each item below and initial in the space provided if you understand each item and agree to follow your doctor's instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not take isotretinoin if there is anything that you do not understand about all the information you have received about using isotretinoin.

1. I, _____
(Patient's Name)

   understand that isotretinoin is a medicine used to treat severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, severe nodular acne can lead to permanent scars.

   Initials: _____

2. My doctor has told me about my choices for treating my acne.

   Initials: _____

3. I understand that there are serious side effects that may happen while I am taking isotretinoin. These have been explained to me. These side effects include serious birth defects in babies of pregnant patients. [Note: There is a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)].

   Initials: _____

4. I understand that some patients, while taking isotretinoin or soon after stopping isotretinoin, have become depressed or developed other serious mental problems. Symptoms of depression include sad, "anxious" or empty mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent. No one knows if isotretinoin caused these behaviors or if they would have happened even if the person did not take isotretinoin. Some people have had other signs of depression while taking isotretinoin (see #7).

   Initials: _____

5. Before I start taking isotretinoin, I agree to tell my doctor if I have ever had symptoms of depression (see #7), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems. Being psychotic means having a loss of contact with reality, such as hearing voices or seeing things that are not there.

   Initials: _____

6. Before I start taking isotretinoin, I agree to tell my doctor if, to the best of my knowledge, anyone in my family has ever had symptoms of depression, been psychotic, attempted suicide, or had any other serious mental problems.

   Initials: _____

7. Once I start taking isotretinoin, I agree to stop using isotretinoin and tell my doctor right away if any of the following signs and symptoms of depression or psychosis happen. I:
   - Start to feel sad or have crying spells
   - Lose interest in activities I once enjoyed
   - Sleep too much or have trouble sleeping
   - Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
   - Have a change in my appetite or body weight
   - Have trouble concentrating
   - Withdraw from my friends or family
   - Feel like I have no energy
   - Have feelings of worthlessness or guilt
   - Start having thoughts about hurting myself or taking my own life (suicidal thoughts)
   - Start acting on dangerous impulses
   - Start seeing or hearing things that are not real

   Initials: _____

8. **I agree to return to see my doctor every month I take isotretinoin to get a new prescription for isotretinoin, to check my progress, and to check for signs of side effects.**

   Initials: _____

9. Isotretinoin will be prescribed just for me — I will not share isotretinoin with other people because it may cause serious side effects, including birth defects.

   Initials: _____

10. I will not give blood while taking isotretinoin or for 1 month after I stop taking isotretinoin. I understand that if someone who is pregnant gets my donated blood, her baby may be exposed to isotretinoin and may be born with serious birth defects.

    Initials: _____

11. I have read *The iPLEDGE Program Patient Introductory Brochure* and other materials my provider provided me containing important safety information about isotretinoin. I understand all the information I received.

    Initials: _____

12. My doctor and I have decided I should take isotretinoin. I understand that I must be qualified in the iPLEDGE Program to have my prescription filled each month. I understand that I can stop taking isotretinoin at any time. I agree to tell my doctor if I stop taking isotretinoin.

    Initials: _____

I now allow my doctor _____ to begin my treatment with isotretinoin.

Patient Signature: _____ Date: _____

Parent/Guardian Signature (if under age 18): _____ Date: _____

Patient Name (print) _____

Patient Address _____ Telephone _____ – _____ – _____

I have:

- fully explained to the patient, _____, the nature and purpose of isotretinoin treatment, including its benefits and risks
- provided the patient the appropriate educational materials, *The iPLEDGE Program Patient Introductory Brochure* and asked the patient if he/she has any questions regarding his/her treatment with isotretinoin
- answered those questions to the best of my ability

Doctor Signature: _____ Date: _____

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

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Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)

TO BE COMPLETED BY THE PATIENT (AND HER PARENT OR GUARDIAN* IF PATIENT IS UNDER AGE 18) AND SIGNED BY HER DOCTOR.

READ EACH ITEM BELOW AND INITIAL IN THE SPACE PROVIDED TO SHOW THAT YOU UNDERSTAND EACH ITEM AND AGREE TO FOLLOW YOUR DOCTOR'S INSTRUCTIONS. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

*A PARENT OR GUARDIAN OF A MINOR PATIENT (UNDER AGE 18) MUST ALSO READ AND INITIAL EACH ITEM BEFORE SIGNING THE CONSENT.

_____
(PAT ENTS NAME)

1. I UNDERSTAND THAT THERE IS A VERY HIGH CHANCE THAT MY UNBORN BABY COULD HAVE SEVERE BIRTH DEFECTS IF I AM PREGNANT OR BECOME PREGNANT WHILE TAKING ISOTRETINOIN. THIS CAN HAPPEN WITH ANY AMOUNT AND EVEN IF TAKEN FOR SHORT PERIODS OF TIME. THIS IS WHY I MUST NOT BE PREGNANT WHILE TAKING ISOTRETINOIN.
   NITIAL: _____
2. I UNDERSTAND THAT I MUST NOT GET PREGNANT 1 MONTH BEFORE, DURING THE ENTIRE TIME OF MY TREATMENT, AND FOR 1 MONTH AFTER THE END OF MY TREATMENT WITH ISOTRETINOIN.
   NITIAL: _____
3. I UNDERSTAND THAT I MUST AVOID SEXUAL INTERCOURSE COMPLETELY, OR I MUST USE 2 SEPARATE, EFFECTIVE FORMS OF BIRTH CONTROL (CONTRACEPTION) **at the same time**. THE ONLY EXCEPTIONS ARE IF I HAVE HAD SURGERY TO REMOVE THE UTERUS (A HYSTERECTOMY) OR BOTH OF MY OVARIES (BILATERAL OOPHORECTOMY), OR MY DOCTOR HAS MEDICALLY CONFIRMED THAT I AM POST-MENOPAUSAL.
   NITIAL: _____
4. I UNDERSTAND THAT HORMONAL BIRTH CONTROL PRODUCTS ARE AMONG THE MOST EFFECTIVE FORMS OF BIRTH CONTROL. COMBINATION BIRTH CONTROL PILLS AND OTHER HORMONAL PRODUCTS INCLUDE SKIN PATCHES, SHOTS, UNDER-THE-SKIN IMPLANTS, VAGINAL RINGS, AND INTRAUTERINE DEVICES (IUDS). ANY FORM OF BIRTH CONTROL CAN FAIL. THAT IS WHY I MUST USE 2 DIFFERENT BIRTH CONTROL METHODS AT THE SAME TIME, STARTING 1 MONTH BEFORE, DURING, AND FOR 1 MONTH AFTER STOPPING THERAPY EVERY TIME I HAVE SEXUAL INTERCOURSE, EVEN IF 1 OF THE METHODS I CHOOSE IS HORMONAL BIRTH CONTROL.
   NITIAL: _____
5. I UNDERSTAND THAT THE FOLLOWING ARE EFFECTIVE FORMS OF BIRTH CONTROL:

PRIMARY FORMS	SECONDARY FORMS
• TUBAL STER LIZATION (TYING YOUR TUBES) • PARTNER'S VASECTOMY • NTRAUTERINE DEVICE • **hormonal (combination birth control pills, skin patches, shots, under-the-skin) implants, or vaginal ring)**	*Barrier forms* • MALE LATEX CONDOM WITH OR WITHOUT SPERMIC DE • DIAPHRAGM WITH SPERMICIDE • CERVICAL CAP WITH SPERMICIDE *Others:* • VAGINAL SPONGE (CONTAINS SPERMICIDE)

   A DIAPHRAGM AND CERVICAL CAP MUST EACH BE USED WITH SPERMICIDE, A SPECIAL CREAM THAT KILLS SPERM

   I UNDERSTAND THAT AT LEAST 1 OF MY 2 FORMS OF BIRTH CONTROL MUST BE A PRIMARY METHOD.
   NITIAL: _____
6. I WILL TALK WITH MY DOCTOR ABOUT ANY MEDICINES INCLUDING HERBAL PRODUCTS I PLAN TO TAKE DURING MY ISOTRETINOIN TREATMENT BECAUSE HORMONAL BIRTH CONTROL METHODS MAY NOT WORK IF I AM TAKING CERTAIN MEDICINES OR HERBAL PRODUCTS.
   NITIAL: _____
7. I MAY RECEIVE A FREE BIRTH CONTROL COUNSELING SESSION FROM A DOCTOR OR OTHER FAMILY PLANNING EXPERT. MY ISOTRETINOIN DOCTOR CAN GIVE ME AN ISOTRETINOIN PATIENT REFERRAL FORM FOR THIS FREE CONSULTATION.
   NITIAL: _____
8. I MUST BEGIN USING THE BIRTH CONTROL METHODS I HAVE CHOSEN AS DESCRIBED ABOVE AT LEAST 1 MONTH BEFORE I START TAKING ISOTRETINOIN.
   INITIAL: _____
9. I CANNOT GET MY FIRST PRESCRIPTION FOR ISOTRETINOIN UNLESS MY DOCTOR HAS TOLD ME THAT I HAVE 2 NEGATIVE PREGNANCY TEST RESULTS. THE FIRST PREGNANCY TEST SHOULD BE DONE WHEN MY DOCTOR DECIDES TO PRESCRIBE ISOTRETINOIN. THE SECOND PREGNANCY TEST MUST BE DONE IN A LAB DURING THE FIRST 5 DAYS OF MY MENSTRUAL PERIOD RIGHT BEFORE STARTING ISOTRETINOIN THERAPY TREATMENT, OR AS INSTRUCTED BY MY DOCTOR. I WILL THEN HAVE 1 PREGNANCY TEST; IN A LAB:
   - EVERY MONTH DURING TREATMENT
   - AT THE END OF TREATMENT
   - AND 1 MONTH AFTER STOPPING TREATMENT

   I MUST NOT START TAKING ISOTRETINOIN UNTIL I AM SURE THAT I AM NOT PREGNANT, HAVE NEGATIVE RESULTS FROM 2 PREGNANCY TESTS, AND THE SECOND TEST HAS BEEN DONE IN A LAB.
   INITIAL: _____
10. I have read and understand the materials my doctor has provided to me, including *The iPLEDGE Program Guide for Isotretinoin for Female Patients Who Can Get Pregnant, The iPLEDGE Birth Control Workbook* and *The iPLEDGE Program Patient Introductory Brochure.*

    MY DOCTOR PROV DED ME AND ASKED ME TO WATCH A V DEO ABOUT B RTH CONTROL AND A VIDEO ABOUT BIRTH DEFECTS AND ISOTRETINOIN.

    I WAS TOLD ABOUT A PRIVATE COUNSELING LINE THAT I MAY CALL FOR MORE INFORMATION ABOUT BIRTH CONTROL. I HAVE RECEIVED INFORMATION ON EMERGENCY BIRTH CONTROL.
    INITIAL: _____
11. I MUST STOP TAKING ISOTRETINOIN RIGHT AWAY AND CALL MY DOCTOR IF I GET PREGNANT, MISS MY EXPECTED MENSTRUAL PERIOD, STOP USING BIRTH CONTROL, OR HAVE SEXUAL INTERCOURSE WITHOUT USING MY 2 BIRTH CONTROL METHODS AT ANY TIME.
    INITIAL: _____
12. MY DOCTOR PROVIDED ME INFORMATION ABOUT THE PURPOSE AND IMPORTANCE OF PROVIDING NFORMATION TO THE PLEDGE PROGRAM SHOULD I BECOME PREGNANT WH LE TAK NG ISOTRETINOIN OR WITHIN ONE MONTH OF THE LAST DOSE. I UNDERSTAND THAT IF I BECOME PREGNANT, INFORMATION ABOUT MY PREGNANCY, MY HEALTH, AND MY BABY'S HEALTH MAY BE SHARED WITH THE MAKERS OF ISOTRETINOIN, AUTHORIZED PARTIES WHO MAINTAIN THE IPLEDGE PROGRAM FOR THE MAKERS OF ISOTRETINOIN, AND GOVERNMENT HEALTH REGULATORY AUTHORITIES.
    INITIAL: _____
13. I UNDERSTAND THAT BEING QUALIFIED TO RECEIVE ISOTRETINOIN IN THE IPLEDGE PROGRAM MEANS THAT I:
    - HAVE HAD 2 NEGATIVE URINE OR BLOOD PREGNANCY TESTS BEFORE RECEIVING THE FIRST ISOTRETINOIN PRESCRIPTION. THE SECOND TEST MUST BE DONE IN A LAB. I MUST HAVE A NEGATIVE RESULT FROM A URINE OR BLOOD PREGNANCY TEST DONE IN A LAB REPEATED EACH MONTH BEFORE I RECEIVE ANOTHER ISOTRETINOIN PRESCRIPTION.
    - HAVE CHOSEN AND AGREED TO USE 2 FORMS OF EFFECTIVE BIRTH CONTROL AT THE SAME TIME. AT LEAST 1 METHOD MUST BE A PRIMARY FORM OF BIRTH CONTROL, **unless I have chosen never to have sexual contact with a male (abstinence)**, OR I HAVE UNDERGONE A HYSTERECTOMY. I MUST USE 2 FORMS OF BIRTH CONTROL FOR AT LEAST 1 MONTH BEFORE I START ISOTRETINOIN THERAPY, DURING THERAPY, AND FOR 1 MONTH AFTER STOPPING THERAPY. I MUST RECEIVE COUNSELING, REPEATED ON A MONTHLY BASIS, ABOUT BIRTH CONTROL AND BEHAVIORS ASSOCIATED WITH AN INCREASED RISK OF PREGNANCY.
    - HAVE SIGNED A PATIENT INFORMATION/INFORMED CONSENT ABOUT BIRTH DEFECTS (FOR FEMALE PATIENTS WHO CAN GET PREGNANT) THAT CONTAINS WARNINGS ABOUT THE CHANCE OF POSSIBLE BIRTH DEFECTS IF I AM PREGNANT OR BECOME PREGNANT AND MY UNBORN BABY IS EXPOSED TO ISOTRETINOIN.
    - HAVE INTERACTED WITH THE IPLEDGE PROGRAM BEFORE STARTING ISOTRETINOIN AND ON A MONTHLY BASIS TO ANSWER QUESTIONS ON THE PROGRAM REQUIREMENTS AND TO ENTER MY TWO CHOSEN FORMS OF BIRTH CONTROL.

    INITIAL: _____

My doctor has answered all my questions about isotretinoin and I understand that it is my responsibility not to get pregnant 1 month before, during isotretinoin or for 1 month after I stop taking isotretinoin.

INITIAL: _____

I NOW AUTHORIZE MY DOCTOR _____ TO BEG N MY TREATMENT WITH ISOTRETINO N.

PATIENT SIGNATURE: _____ DATE: _____

PARENT/GUARDIAN SIGNATURE (IF UNDER AGE 18): _____ DATE: _____

PLEASE PR NT: PAT ENT NAME AND ADDRESS _____ TELEPHONE _____

I HAVE FULLY EXPLAINED TO THE PATIENT, _____, THE NATURE AND PURPOSE OF THE TREATMENT DESCRIBED ABOVE AND THE RISKS TO FEMALE PAT ENTS OF REPRODUCTIVE POTENTIAL. I HAVE ASKED THE PATIENT IF SHE HAS ANY QUESTIONS REGARDING HER TREATMENT WITH ISOTRETINOIN AND HAVE ANSWERED THOSE QUESTIONS TO THE BEST OF MY ABILITY.

DOCTOR SIGNATURE: _____ DATE: _____

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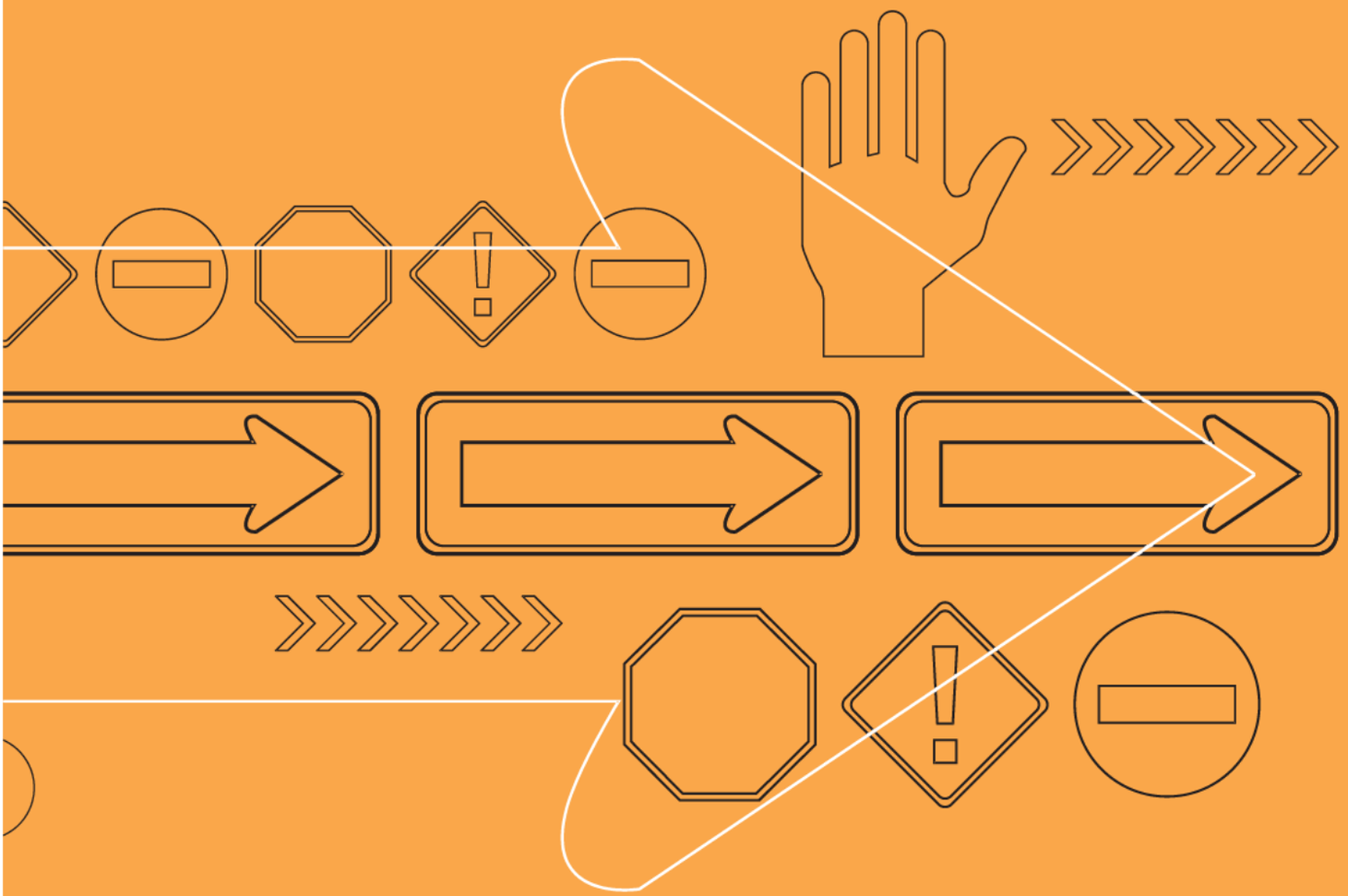
PRE_FORM02 SEP 15

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

Reference ID: 3956479

Patient Flowchart



A flowchart to assist you with the iPLEDGE Program requirements

Reference ID: 3956479

REGISTERED PATIENTS

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Females of reproductive potential (FRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Sign** a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- **Get** a screening urine/blood pregnancy test
- **Receive** patient ID card
- **Choose** 2 effective forms of birth control
- **Start** using the 2 forms of birth control simultaneously for at least 1 month
- **Get** a second pregnancy test within the first 5 days of your menstrual period (patient with irregular cycle please check with your prescriber) in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and to enter the 2 chosen forms of birth control. You can only answer your questions after your doctor has entered your test results into the iPLEDGE Program System
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **Use** the 2 forms of birth control Simultaneously
- **See** your doctor for a monthly pregnancy test in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and confirm the 2 forms of birth control
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Get** a pregnancy test in an approved lab the last dose
- **Continue** to use the 2 forms of birth control simultaneously for 1 month after the last dose
- **Do not** donate blood for 1 month after the last dose
- **Get** a final pregnancy test 1 month after the last dose

Male patients/Females of non-reproductive potential (FNRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Receive** patient ID card
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **See** your doctor to get a prescription
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Do not** donate blood for 1 month after after your last dose

*You can access the system via the web site, **www ipledgeprogram.com**, or the telephone, **1-866-495-0654**.

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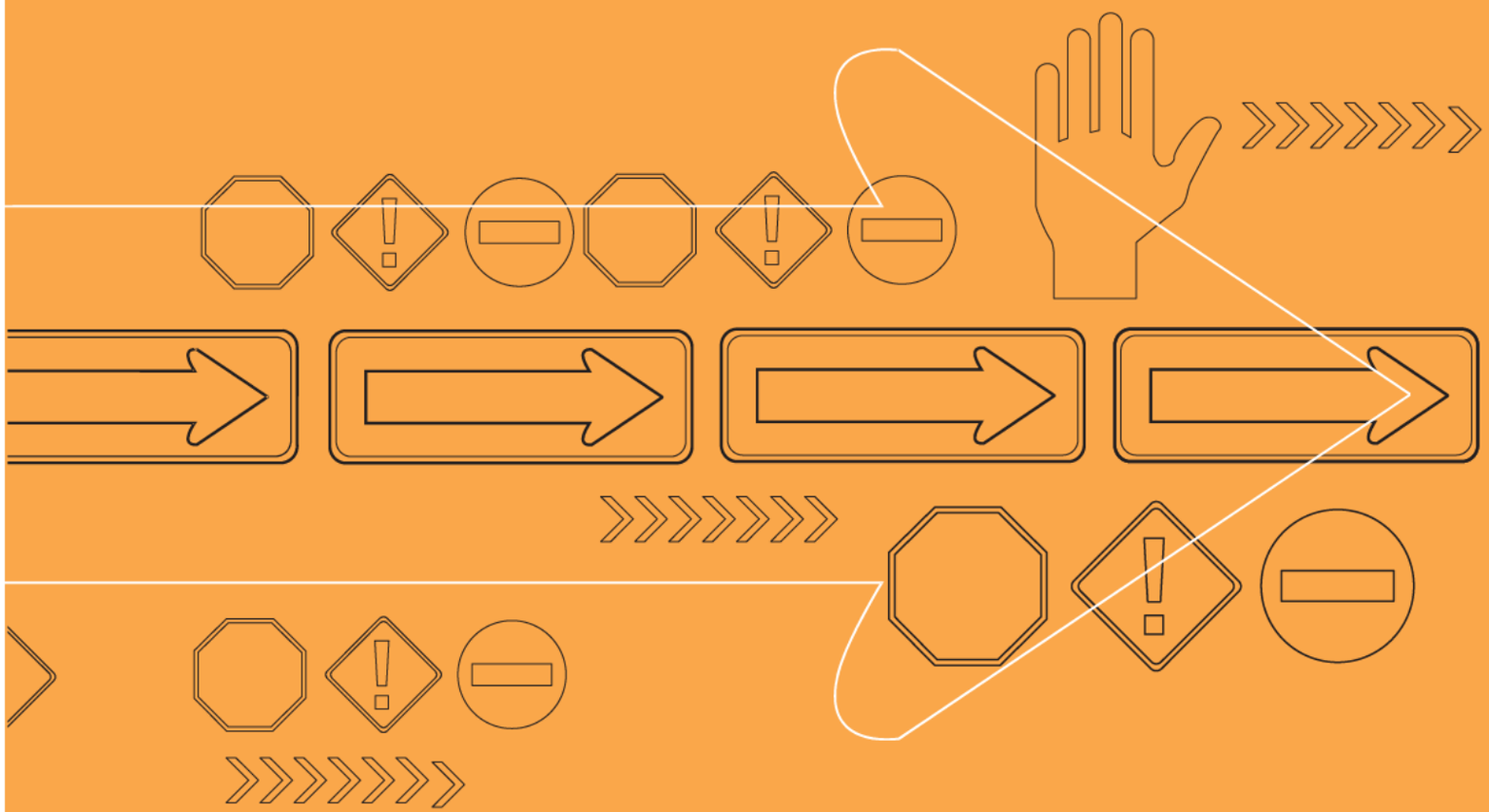

www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Reference ID: 3956479

Most Recent Modification: July 2016

The iPLEDGE Program

Guide To Isotretinoin For Patients Who Can Get Pregnant

The Importance Of Avoiding Pregnancy On Isotretinoin

The resource to help you prepare, plan treatments, and prevent pregnancies during the course of isotretinoin treatment

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

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ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin. The program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and the other materials in this educational kit. Your doctor also has an educational video for you to watch.

Make sure you understand the requirements of the iPLEDGE Program. Then, decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR FEMALE PATIENTS WHO CAN GET PREGNANT

Here are 2 key messages of the iPLEDGE Program:

Do NOT take isotretinoin if you are pregnant.

Do NOT get pregnant before starting isotretinoin, while taking it, and for 1 month after your last dose.

If you get pregnant while taking isotretinoin, there is a very high chance that your baby will be deformed, born too early, or die before being born. This can happen even if you only take isotretinoin for a short time.

Prevent Pregnancy And Birth Defects

Here are some key steps you must follow in the iPLEDGE Program to take isotretinoin:

Have 2 negative pregnancy tests before you start isotretinoin.

Have a negative pregnancy test before you obtain each monthly prescription.

Use 2 forms of birth control together.

Reference ID: 3956479

You must use 2 forms of birth control together correctly all the time for 1 month before you start isotretinoin, while you are taking isotretinoin, and for 1 month after your last dose. These forms of birth control must be effective in the iPLEDGE Program.

Any form of birth control can fail. Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.

Your doctor will talk with you about birth control or refer you to a gynecologist, a family doctor, or a birth control expert for counseling.

Reasons you would not have to use 2 forms of birth control

There are 2 reasons you would not have to use 2 effective forms of birth control.

- You commit to not having any heterosexual sexual intercourse with a male for 1 month before, during, and for 1 month after your isotretinoin treatment (abstinence).
- You are unable to get pregnant because:
  - You have entered menopause, and your doctor has confirmed this.
  - You have had both of your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant woman receives blood that you donated. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 14 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

Reference ID: 3956479

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant and your patient educational kit are resources for the information you need about isotretinoin and the iPLEDGE Program. The iPLEDGE Program also has a web site and an automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE Program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID card, and other program materials. You use these to log in to the system *(see page 9)*. You will use the system to meet some of the monthly requirements of the program.

After you have been registered in the iPLEDGE Program by your doctor, you will receive your iPLEDGE password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE Program system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant explains the key information about the iPLEDGE Program before, during, and after your isotretinoin treatment. Here is a general overview:

1. Learn about the iPLEDGE Program and the isotretinoin side effects and risks in pregnancy.
2. Sign the Patient Information/Informed Consent forms.
3. Plan for treatment and for monthly appointments and pregnancy tests.
4. Choose 2 forms of effective birth control for the iPLEDGE Program; use them all of the time.
5. Take blood or urine pregnancy tests.
6. Answer monthly educational questions to show you understand the iPLEDGE Program and about preventing pregnancy.
7. Follow requirements for pregnancy testing and follow-up after your last dose.
8. Do not donate blood during your treatment or for 1 month after your last dose.
9. Do not share isotretinoin.

This information and details of the program are described in the sections to follow. The section on page 6 reviews the forms of effective birth control in the iPLEDGE Program.

You can always use the checklist on the next page as a quick reminder of the program information.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient

Female patients who can get pregnant…

The prescription window is 7 days, and starts on the date that the urine or blood sample *is taken for your pregnancy test. This date is counted as DAY 1.*

To determine the end date of your 7-day prescription window, you should add 6 days to the date of the blood or urine sample being taken.

After 11:59 p.m. Eastern Time on the last day of the 7-day prescription window, you can no longer obtain your prescription, and must start the process over to get a new 7-day prescription window.

All patients have a specific period of time in which they can Obtain their prescription.

Before Starting Treatment

PLANNING

- ❑ **Plan** your course of treatment (about 4 to 5 months). (*see page 8*)
- ❑ **Talk** with your doctor about the iPLEDGE Program.
- ❑ **Sign** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Have** your first urine or blood pregnancy test, which can be performed at the doctor's office.
- ❑ **Get** your patient ID cards containing your patient ID number from your doctor. (*see page 8*)

BIRTH CONTROL (*see page 6*)

- ❑ **Read** *The iPLEDGE Program Birth Control Workbook*.
- ❑ **Talk** with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options.
- ❑ **Choose** 2 effective forms of birth control.
- ❑ **Start** using the 2 forms of birth control together for at least 1 month before you start isotretinoin.

YOUR FIRST PRESCRIPTION

- ❑ **Have** a second pregnancy test within the first 5 days of your menstrual period (at least 30 days after registration).
- ❑ **Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form. (*see page 9*)
- ❑ **Answer** questions about the iPLEDGE Program and confirm your 2 forms of birth control. (see page 10) This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.
- ❑ **Obtain** your prescription for up to a maximum of a 1-month supply. (*see page 11*)
- ❑ Obtain your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1. (*see page 12*)
  - If you are not able to obtain your first prescription within the 7-day prescription window, you will be required to wait a minimum of 19 days before you can start this process again.
- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ Answer different questions each month about the iPLEDGE Program.

Reference ID: 3956479

During Treatment

- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **Confirm** your 2 forms of birth control by entering them into the iPLEDGE Program System. (see page 10)
- ❑ **Answer** different questions each month about the iPLEDGE Program. **This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- ❑ **Obtain** your prescription for up to a maximum of a 30-day supply. *(see page 11)*
- ❑ **Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1. (*see page 12*)
  - If you do not obtain your prescription within the 7-day prescription window, you will need to go back to your doctor to start this process again.
- ❑ **Do not donate** blood.

After Treatment

RIGHT AFTER YOUR LAST DOSE (*see page 13*)

- ❑ **Get** a pregnancy test after your last dose.
- ❑ **Continue** using your birth control for 1 month.
- ❑ **Do not donate** blood for 1 month after your last dose.
- ❑ **Ensure** that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

1 MONTH AFTER YOUR LAST DOSE

- ❑ **Have** a final pregnancy test at 1 month after your last dose.
- ❑ Ensure that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

EFFECTIVE FORMS OF BIRTH CONTROL

Not all forms of birth control are acceptable while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read The iPLEDGE Program Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read *The iPLEDGE Program Birth Control Workbook*. Discuss this information with someone you trust. Discuss it with your partner. Think about what forms of birth control you would really use, and then talk with your doctor or a birth control expert.

Reference ID: 3956479

Talk With An Expert

If you want to talk to a birth control expert, your gynecologist, or family doctor about birth control, the doctor who prescribes isotretinoin for you can refer you. The makers of isotretinoin will pay for a visit for you to talk about birth control. *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* is in this booklet.

- Make an appointment with a birth control expert, your gynecologist, or family doctor.
- Take *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* with you. It has important information that the birth control expert, gynecologist, or family doctor needs to talk about, including the forms of effective birth control for the iPLEDGE Program.
- The healthcare professional providing contraception counseling will fill out the Contraception Referral Form included in the guide after he/she talks with you and then mail or fax it back to the doctor who prescribes your isotretinoin.

Changing Your Birth Control

If you need to change forms of birth control during your isotretinoin treatment, you need to tell the doctor who prescribes your isotretinoin. You do not want to take isotretinoin if you are not protected against pregnancy all the time.

You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been on the new form for at least 1 month and have a negative pregnancy test.

Changing From Abstinence

If you have been abstinent (not having any sexual activity) and you decide to start having sexual activity, you must tell the doctor who prescribes your isotretinoin. You and your doctor must make a plan to start birth control and be sure you are not pregnant before you continue isotretinoin.

One of the most common reasons that women get pregnant is that they do not avoid sexual activity when they plan to be abstinent.

Video: *Be Prepared, Be Protected, And Be Aware: The Risk Of Pregnancy While On Isotretinoin*

Your doctor has a video that shows the kinds of birth defects that may happen if a woman takes any amount of isotretinoin while she is pregnant. It also reviews the steps for preventing pregnancy.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST INFORMATION

Plan Your Course Of Treatment

Birth Control and Pregnancy tests

Before you can begin isotretinoin therapy, there is a 30-day wait period where you must be on two forms of birth control. Additionally, you need to have 2 negative pregnancy tests. They can be urine or blood tests. You will need to plan with your doctor when and where to take your pregnancy tests.

- You take the first test when you decide to take isotretinoin.
- You take the second test during the first 5 days of the menstrual period right before you start isotretinoin. This pregnancy test must be done by an approved lab. The interval between the two tests must be at least 19 days.

You also take a pregnancy test every month done by an approved lab during treatment. You also take a pregnancy test after your last dose, and 1 month after your last dose. You will need to plan with your doctor when to take your pregnancy test each month.

Prescriptions

The most isotretinoin you can get at any one time is up to a maximum of a 30-day supply. You will need to see your doctor each month to get a new prescription, and meet the monthly program requirements.

Get Your Patient ID Number And Cards

Your doctor will give you your patient ID number and cards when you start the iPLEDGE Program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. It is important not to lose these cards. Write your number down as soon as you receive it and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled at the pharmacy
- When you log in to the iPLEDGE Program automated system, either the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**

Reference ID: 3956479

About The iPLEDGE Program Automated System

The first time you login to the iPLEDGE Program (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using the iPLEDGE Program system.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can obtain up your prescription
- Change to a new doctor
- Get information about isotretinoin
- Answer your Comprehension Questions, required before you can obtain your prescription
- View information about your current status, your 7-day prescription window, and next steps required in the program
- View FAQ's (Frequently Asked Questions)

If you lose your patient ID cards, and cannot remember your patient ID number, contact your doctor.

Informed Consents

You sign 2 consent forms to be in the iPLEDGE Program.

1. **Patient Information/Informed Consent (for all patients)**

Signing the Patient Information/Informed Consent (for all patients) form means you understand that there are risks with isotretinoin.

2. **Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)**

Your doctor will talk to you about the risks of isotretinoin during pregnancy. You must also get this information in writing. You must understand that a baby exposed to isotretinoin could have severe birth defects. Signing the consent form means the following:

- You understand the risks of isotretinoin for unborn babies.
- You agree to use 2 effective forms of birth control, as the iPLEDGE Program requires. *The iPLEDGE Program Birth Control Workbook* has the list of effective forms.

Reference ID: 3956479

The iPLEDGE Program Pregnancy Registry

Because isotretinoin causes such severe birth defects, it is very important for us to know about all the pregnancies that happen during treatment and within 1 month after the last dose. If you think you are pregnant call your doctor. The confidential iPLEDGE Program Pregnancy Registry is a way to collect that information. It may help us prevent more pregnancies in the future.

Your doctor will tell you about the confidential iPLEDGE Program Pregnancy Registry. You are encouraged to contact the iPLEDGE Program Pregnancy Registry at 1-800-681- 7247 if you get pregnant.

Answering Questions About The iPLEDGE Program And Preventing Pregnancy

The iPLEDGE Program requires you to answer comprehension questions before obtaining every prescription. These questions will demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. **You will not be able to answer your questions until your doctor has entered your pregnancy test result in the iPLEDGE Program System.** You may not obtain up your prescription until you have correctly answered the questions. You may use your iPLEDGE Program educational kit as a resource as you answer the questions.

Your First Month Taking Isotretinoin

The first month that you answer your questions, you will be asked a series of questions about iPLEDGE Program information and counseling provided to you. There are no wrong answers to these questions. The answers are used to determine how often the iPLEDGE Program materials are shared with patients.

Birth Control Verification

You must enter the 2 forms of birth control you are using. Your doctor will also separately enter the 2 forms of birth control you told him or her you are using. This information must be in the iPLEDGE Program system and must match for you to obtain your prescription.

Comprehension Questions

Before each prescription can be obtained from the pharmacy, you will have different questions about the iPLEDGE Program and preventing pregnancy to answer. You answer the questions in the iPLEDGE Program system using the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654** within the 7-day prescription window.

Reference ID: 3956479

You can use *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and *The iPLEDGE Program Birth Control Workbook* to help you with the answers.

You need your patient ID number and password to log in to the iPLEDGE Program system.

To answer questions on the iPLEDGE Program web site:

1. Log in
2. Click on the button under "Answer the Questions"
3. Enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

To answer the questions on the iPLEDGE Program phone system:

1. Log in
2. Select the option to "Demonstrate Your Program Knowledge"
3. Follow the prompts to enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

The system will let you know if you answered correctly. If you missed any questions, you will get to try other questions like the ones you missed. You must answer the questions correctly before you will be able to obtain your prescription.

If you miss a question again, the system will tell you where to look in *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* or *The iPLEDGE Program Birth Control Workbook* to find answers. You can answer the questions again later. You may also talk with your doctor about questions you missed.

Obtain Your Prescription

Obtain your isotretinoin prescriptions only from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com**, has a list of registered and activated pharmacies. Log in and choose "Finding a Participating Pharmacy" on the Patient home page.

The pharmacist will contact the iPLEDGE Program system before filling the prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only obtain your prescription for isotretinoin if:

- Your pregnancy test was negative
- Your doctor entered your 2 forms of birth control in the iPLEDGE Program system

Reference ID: 3956479

- You answered your questions correctly. **This can only be done after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- You also entered your 2 forms of birth control

You **obtain** the prescription within the 7-day prescription window (1 week) of the date of your pregnancy test, counting the date of the pregnancy test as DAY 1.

To figure out the last date you can obtain your prescription, add 6 to the date of your pregnancy test. For example:

Day 1 pregnancy test	Day 2 – Day 6	Day 7 – Last day obtain Day of the up prescription
(Friday, March 1)	(Saturday–Wednesday)	(Thursday, March 7)

The 7-day prescription window expires at 11:59 p.m. Eastern Time on Day 7 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 7-day prescription window expires before you obtain your prescription, you can start a new 7-day prescription window right away (unless it is your first prescription window), but you must repeat the program requirements to get another prescription. Additional information regarding the specific dates of your 7-day prescription window, and other information about your current status can be found by selecting "My Program Status" on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479

After Your Last Dose

It is very important that you:

- Get a pregnancy test.
- Keep using 2 effective forms of birth control together all the time for 1 month after your last dose. It takes time for isotretinoin to leave your bloodstream.
- Go back to your doctor 1 month after your last dose for your last pregnancy test, even if you think you are not pregnant. If you miss this appointment, you will receive a reminder notification.
- Do not give blood for 1 month after your last dose.
- If your doctor does not enter the results of the pregnancy test after your last dose, and does not enter the pregnancy test 1 month after your last dose, both you and your doctor will be contacted for additional information.

Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE Program system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE Program web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**. You need your patient ID number to log in to the system.

To change your doctor on the iPLEDGE Program web site:

1. Log in
2. Choose "Change Primary Prescriber" from the menu
3. You need to enter the following information about your new doctor:
   - First and last name
   - City
   - Phone number

To change your doctor on the automated phone line:

1. Log in
2. Select the Option for "More Choices"
3. Select the Option to "Change Your Prescriber"
4. Follow the prompts to enter the new information

The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE Program system before being able to give you a prescription.

Reference ID: 3956479

Safety Information

ABOUT ISOTRETINOIN

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
   Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
     Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Reference ID: 3956479

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

Reference ID: 3956479

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule. Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do not take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control. To access the iPLEDGE Program system, go to www.ipledgeprogram.com or call 1-866-495-0654.

Reference ID: 3956479

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

Reference ID: 3956479

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Reference ID: 3956479

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children.**

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.

Reference ID: 3956479

For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, ask your doctor, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call the automated phone line at **1-866-495-0654**.

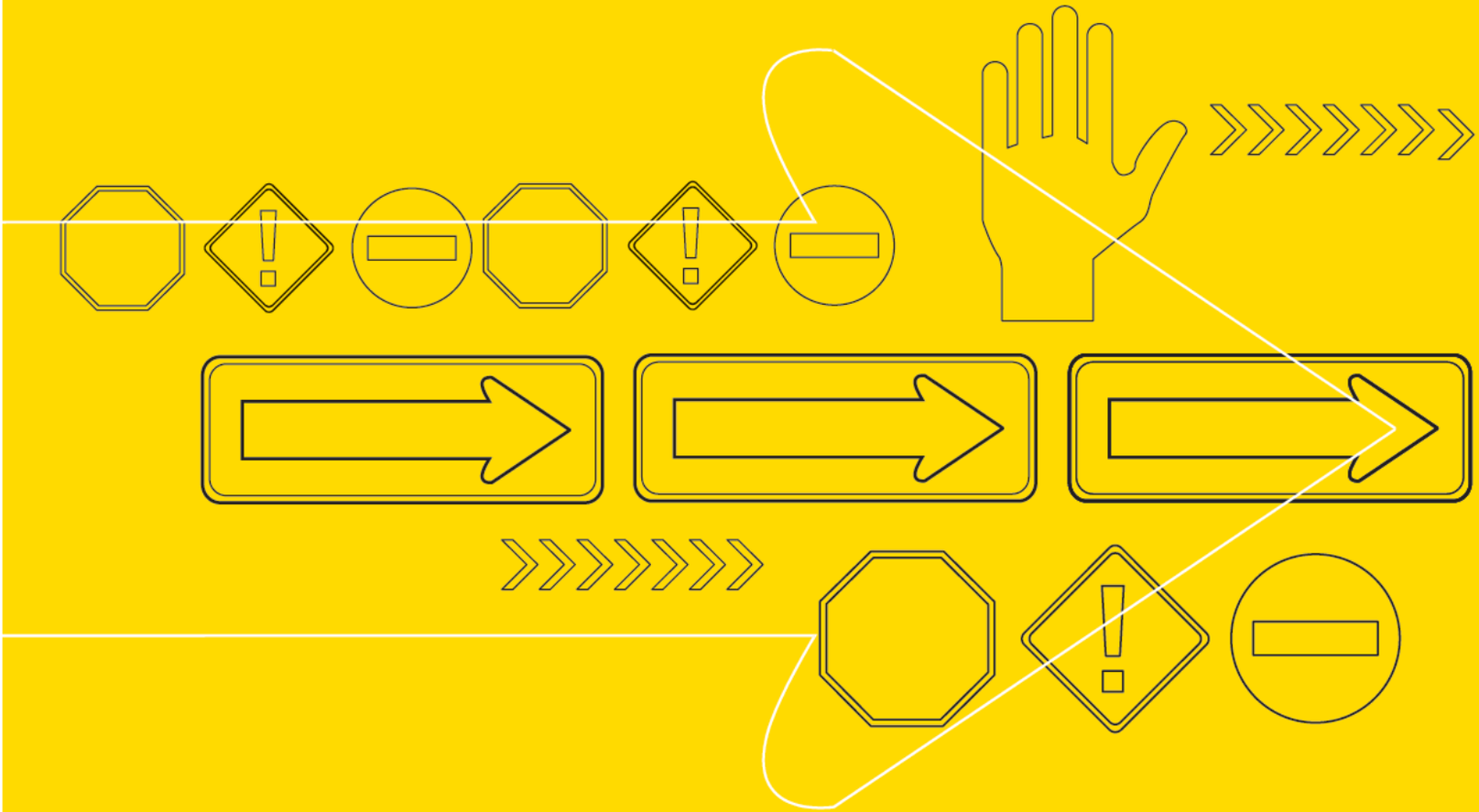
For private birth control information, you can reach the iPLEDGE Program automated phone line 24 hours a day, 7 days a week at 1-866-495-0654. You can learn about different subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™
Committed to Pregnancy Prevention

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Most Recent Modification: July 2016

The iPLEDGE Program

Birth Control Workbook

The guide to help you decide which forms of birth control are best for you during treatment with isotretinoin

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

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PREVENTING PREGNANCIES

Not all forms of birth control are effective while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read This Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read this *iPLEDGE Program Birth Control Workbook*. Read it before you make any decisions about birth control. Read it even if you are already using birth control. Read it even if you think you will not have sex with a male for your whole isotretinoin treatment.

After you have read through the booklet, talk it over with someone you trust. Think about what kinds of birth control you would really use. Then talk with your doctor or a birth control expert.

Share this workbook with your partner. Talk with your partner about birth defects and isotretinoin. Explain what you both need to do to prevent pregnancy. Tell him you need to prevent pregnancy for at least 1 month before you start isotretinoin, during your treatment, and for 1 month after your last dose. This can be several months.

Write down a list of questions for your dermatologist, gynecologist, or family doctor. No question is too silly. Make sure you know how to use the birth control forms you choose.

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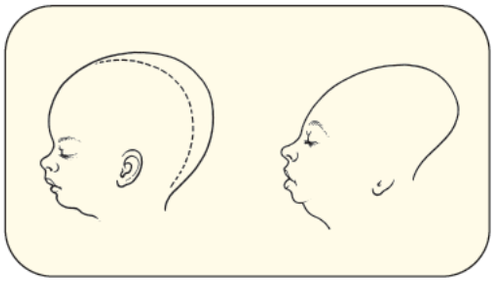
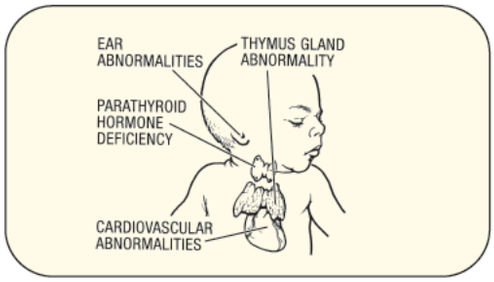
WHY SHOULD I USE THIS WORKBOOK?

You are getting ready to start isotretinoin (eye-soh-tret-in-OH-in). It treats severe acne, but it can also cause birth defects. You must not get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose. **There is a very high chance that your baby could be deformed, born too early, or die.** This can happen even if you take isotretinoin for only a short time.





The pictures show some of the birth defects your baby can have. Your baby's head could be deformed; the ears could be an odd shape or even missing. The eyes could be too far apart, the bridge of the nose too low, or the chin smaller than normal. The baby could have mental retardation or severe problems in the glands, heart, and brain.

You do not want to be pregnant or get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose.

To keep from getting pregnant, you need to use 2 effective forms of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- While you take it—treatment usually lasts 4 to 5 months
- For 1 month after your last dose—you still need protection against pregnancy

This workbook is for ALL female patients who can possibly get pregnant. This means that:

- You are physically able to get pregnant
- You have a uterus and ovaries
- You have menstrual periods

Even if you are not having sex, you still need to follow the requirements of the iPLEDGE Program.

Female Patients Who Cannot Get Pregnant

Female patients who cannot get pregnant are not required to be on birth control. This applies to you if:

- You have entered menopause, and your doctor has confirmed this.
- You have had your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

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HOW SHOULD I USE THIS WORKBOOK?

Use this workbook as a guide to help you decide which 2 effective birth control forms are best for you during your treatment. You will want to pick a birth control form that works for you and gives you the best protection against pregnancy (primary form). Since all forms of birth control can fail, you must also pick a second form (another primary form or a secondary form) that you use every time you have sex.

This workbook also provides information about abstinence, emergency birth control, and issues around conception and pregnancy.

THE iPLEDGE PROGRAM AND BIRTH CONTROL

Referral for birth control counseling

Before beginning treatment, you or the doctor may choose a referral to a birth control expert. The makers of isotretinoin will pay for 1 visit for birth control counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the birth control requirements and the effective forms of birth control of the iPLEDGE Program for the birth control expert. The referral form should be taken with you to the birth control counselor.

Why Do I Have To Use 2 Forms Of Birth Control Together?

- Any single birth control form can fail.
- Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.
- Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control!

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Can I Use Any 2 Forms Of Birth Control?

No, you must choose from the iPLEDGE Program list of effective birth control forms.

The 2 types of birth control you use for the iPLEDGE Program are called **primary forms** and **secondary forms**.

- **Primary forms** do not fail very often. Be sure to choose a primary form that gives you the lowest chance of failure. This depends on such things as how well you remember to take medicine every day, whether you have had children or your partner has had a vasectomy, or you have medical problems.
- **Secondary forms** include **barrier forms** and **other forms** of birth control. The most important thing about a secondary form is using it every time you have sex.
  - **Barrier forms** keep sperm from entering the uterus. Barrier forms include the diaphragm and the cervical cap, both of which must be used with a cream that kills sperm, called a spermicide. The Male Latex Condom is also a Barrier form, and it can be used with or without spermicide.
  - **Other forms** (vaginal sponge) contain spermicide.

Preventing Pregnancy By Abstinence (Not Having Sex)

Abstinence means that you ***will not have sex*** or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do, especially if you are used to having sex.

It is easier not to have sex when it is a lifestyle choice, such as religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence).

If you cannot commit completely to not having sex (abstinence) while taking isotretinoin, you must use 2 separate, effective forms of birth control at the same time. The only exceptions are if you have had surgery to remove your uterus (a hysterectomy) or both of your ovaries (bilateral oophorectomy), or if your doctor has medically confirmed that you are post-menopausal. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.

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Concerns About Birth Control Pills

Many female patients use birth control pills. But birth control pills can fail, and you can get pregnant. They fail because you may forget to take them as directed by your health care provider.

- If you take them about the same time every day, they are very effective birth control.
- If you miss pills and do not take them every day, your chance of getting pregnant is much higher with birth control pills than with other primary birth control forms, such as hormonal shots or an intrauterine device (IUD).

If you are taking birth control pills, do you remember to take them every day? If not you need to consider another primary form of birth control as you read this workbook.

The iPLEDGE Program Effective Birth Control Forms

Effective forms of contraception include both primary and secondary forms of contraception:

Primary forms	Secondary forms
• Tubal sterilization (tying your tubes) • Partner's vasectomy • Intrauterine device • Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier form (used with or without spermicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

You cannot use 2 hormonal forms together. Progesterone-only "mini-pills" are not considered an effective form of birth control for the iPLEDGE Program.

Female condoms are not an effective secondary form of birth control for the iPLEDGE Program.

Reference ID: 3956479

Birth Control Forms That Are NOT Acceptable

You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

- Birth control pills without estrogen (progesterone-only mini-pills)
- Female condoms
  - *A thin, loose-fitting, and flexible plastic tube that you put inside your vagina. It covers your cervix to block sperm.*
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
  - *This means not having sex during certain times of the month when you might be more likely to get pregnant. It does not work.*
- Withdrawal
  - *Your partner can leak enough sperm to get you pregnant even if he does not ejaculate inside you.*
- Cervical shield‡
  - *A silicone disc that sticks to your cervix to keep sperm out.*

Tell your doctor what type of birth control you are using. You will need to change to effective forms if your birth control is listed above. You must use 2 effective forms together all the time for at least 1 month and have a negative pregnancy test.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception. See page 28.

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Ask yourself:

1. Which of the following is NOT one of the effective primary or secondary forms of birth control while taking isotretinoin?
   - A) Partner's vasectomy or tubal sterilization (tying your tubes)
   - B) Natural family planning
   - C) Hormonal IUD
   - D) Cervical cap with spermicide

2. Which of the following are effective forms of birth control for someone on isotretinoin?
   - A) The hormonal skin patch and a male latex condom
   - B) Cervical cap and a male latex condom
   - C) Copper T380A IUD and withdrawal
   - D) Birth control pills and a diaphragm with spermicide

Answer key: page 38

WHY DO I NEED HELP CHOOSING BIRTH CONTROL?

Not every birth control form is good for everyone. Some female patients should not use certain birth control, such as hormones or an IUD. If you are not good at remembering to take medicines, you should not choose birth control pills. Your dermatologist, gynecologist, or family doctor will help you choose the right forms for you. They will also give you exact instructions on how to use them.

Choose forms that you will actually use all the time. Some female patients have found it hard to use 2 forms of birth control together all the time. **This workbook will help you sort through these questions.** It will help you choose the 2 birth control forms that will be best for you. Here are some questions to think about.

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Ask yourself:

- Have you ever used birth control? Did you think you will need to use birth control someday?
- What birth control are you using now? Do you like it and want to continue using it?Is it on the list of effective birth control for the iPLEDGE Program?
- Are you currently having sex?
- Are you ever pressured into sex or think you may be forced to have sex?
- If you are taking birth control pills, do you ever forget to take them? Do you ever take them out of order? Do you always take medications the way you are told?
- Are there any forms of birth control you have heard about and would like to try?
- Can you rely on your partner's cooperation when using birth control, such as getting him to use a male latex condom each time you have sex?
- Are you worried about protecting yourself from STIs (sexually transmitted infections) or HIV (AIDS)?
- Is the cost of birth control a problem for you?
- Do you mind having to stop sex play to use a male latex condom or diaphragm?
- Do you worry about certain forms of birth control?
- Do you ever want to be pregnant?

What If I Cannot Use 2 Forms Of Birth Control Together All The Time?

Talk with your dermatologist, gynecologist, or family doctor. If you plan to have sex during your treatment and feel you cannot be 100% successful in using 2 forms of birth control each time, you should not take isotretinoin.

What If My Birth Control Fails?

The section on "Emergency Birth Control (Emergency Contraception)" is on page 31 of this workbook. It tells you what emergency birth control is and where to get it quickly.

Reference ID: 3956479

MAKING A CHOICE ABOUT BIRTH CONTROL

General Advice

Stay with your current primary form of birth control if:

- You are currently using an effective primary form AND you use it perfectly. For example, you do not miss birth control pills or hormone shots.
- You are satisfied with it.

Talk with your dermatologist, gynecologist, or family doctor about changing birth control before you start isotretinoin treatment if you:

- Do not use your current form of birth control perfectly. For example, you forget to change hormonal skin patches every week.
- Are not satisfied with the birth control you are using now. Changing birth control in the middle of your isotretinoin treatment is difficult.

You need to tell the doctor who prescribes your isotretinoin if you decide to change forms of birth control during treatment. You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been using the new form with a second form for at least 1 month and have a negative pregnancy test.

Planning Ahead With Your Partner

You want your partner to support you as you go through isotretinoin treatment. It is a great idea to talk with him about the iPLEDGE Program before you start. Do not surprise him later.

1. Talk to him about why you decided to take isotretinoin at this time.
2. You will want him to agree with and support your decision to have this treatment.
3. Make sure he knows all the facts about isotretinoin and birth defects. Show him the patient information. Your partner needs to understand all the facts about isotretinoin. He needs to be aware of what good it can do, as well as its risks.
4. Make sure he knows you have to use 2 forms of birth control together correctly all the time for at least 1 month before beginning isotretinoin treatment, during treatment for several months, and 1 month after the last dose of isotretinoin.
5. Make sure he is willing to go along with the iPLEDGE Program for several months.

You could ask your partner:

1. To help you make a list of questions to ask your doctor
2. To come with you to a doctor's office visit
3. To help you choose the 2 forms of birth control you will be using

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Ask yourself:

1. Your doctor tells you that you need to have a pregnancy test before you can obtain a prescription. You would:
   - A) Refuse the test because you know you are not pregnant
   - B) Ask your doctor to explain why you need the test
   - C) Go to another doctor to get isotretinoin

2. I need to use 2 separate, effective forms of birth control at the same time while on isotretinoin because:
   - A) There is a high chance for multiple births from taking isotretinoin
   - B) There is a very high chance that my baby will be deformed if I get pregnant
   - C) I may find it hard to not have sex during treatment and 1 month after my last dose

3. You already take birth control pills. If you want to start isotretinoin, you:
   - A) Review this *iPLEDGE Program Birth Control Workbook*, and then get counseling before you choose a second form
   - B) Do not worry about a second form now, because you are not having sex with anyone

Answer key: page 38

PRIMARY FORMS OF BIRTH CONTROL

This section of the workbook provides information about the different forms of primary birth control. It only gives you the most important information you need for the iPLEDGE Program. It does not cover all the side effects or other information about these forms. If you want more information, ask your dermatologist, gynecologist, or family doctor. They have more information written for healthcare professionals and for patients.

None of the primary forms protect against sexually transmitted infections (STIs) or HIV (AIDS).

Hormonal Birth Control Forms

Hormonal birth control forms include combination birth control pills, the skin patch, shots, under-the-skin implants, and the vaginal ring. They are prescription medicines that prevent pregnancy.

Reference ID: 3956479

Hormonal Combination Birth Control Pills

Hormonal combination birth control pills are birth control pills you take by mouth every day as prescribed.

Progesterone-only birth control pills (mini-pills) are not acceptable for the iPLEDGE Program because they are not an effective form of birth control. If you are using these, you will have to choose another primary form of birth control.

Who should not take birth control pills?

You should not use birth control pills if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

Why is it important how I take birth control pills?

Birth control pills provide very good protection only if you take them about the same time every day and do not miss any pills. If you miss pills, your chance of pregnancy is much greater. Your chance of getting pregnant is higher if you miss pills at the beginning of your cycle or start your pills too late in your cycle. Less than half of all females take their birth control pills as prescribed.

- The most important thing about using birth control pills as your primary form of birth control is taking them every day to keep the chance of pregnancy as low as possible. If you have not used them perfectly, you may need to choose another primary form of birth control, such as the hormonal shot, an IUD, or a hormonal skin patch.
- Isotretinoin may make birth control pills less effective. That means you could be more likely to get pregnant while you are taking isotretinoin, particularly if you miss a pill.

Are you taking birth control pills now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you ever have pills left at the end of the month?
- How often do you miss more than 1 pill per cycle? Do you do it more than 2 cycles in a year?
- Have you ever taken birth control pills out of order?

If you answered yes to any of these questions, you probably need to choose another primary form of birth control.

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If you are not taking birth control pills now, why do you think you want to try them? Ask yourself:

- Have you ever had to remember to take a pill every single day?
- Why do you think you can remember this task?

If you do not remember to take your pill every day without fail or have never taken pills every day before, you should probably not use birth control pills during isotretinoin treatment.

Advantages

- You may be able to get pregnant within 3 months after stopping birth control pills.
- Breast cysts may occur less frequently
- May provide some protection against the development of uterine and ovarian cancer

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Disadvantages

- Birth control pills do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- If you skip pills, your chance of pregnancy is very high.
- Isotretinoin, antibiotics, and St. John's Wort may make birth control pills less effective.

What should I do if I miss birth control pills when I am on isotretinoin?

If you miss any birth control pills, do not have sex for the rest of your cycle. You could get pregnant.

- If you miss 1 pill, take it as soon as you remember. Continue taking your other pills at the regular time. Call your doctor as soon as you realize it.
- If the whole day goes by before you realize you missed a pill, it is OK to take 2 pills together.
- **If you miss more than 2 days, you should call your doctor as soon as you realize it.** You are at a greater chance for pregnancy if you start a cycle late or miss taking pills during the first week of each cycle.

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Ask yourself:

1. If your 2 birth control forms are birth control pills and the diaphragm with spermicide, and you forgot to take 2 pills in a row, you should:
   - A) Not worry because you are using a diaphragm with spermicide, too
   - B) Not have sex and call your doctor because you do not have enough protection to keep from getting pregnant
   - C) Take birth control pills 2 at a time until you catch up

2. You are talking to your doctor about having your second pregnancy test, so you can start isotretinoin. You have been on birth control pills for 1 month, and it is the second day of your period. Three days ago, you and your partner forgot to use a male latex condom when you had sex. You should:
   - A) Have the pregnancy test anyway because it will tell you if you are pregnant
   - B) Not worry because you have your period
   - C) Tell the doctor you and your partner forgot to use a male latex condom once
   - D) Not worry because you forgot before and never got pregnant

Answer key: page 38

Hormonal Skin Patch

The hormonal skin patch is a thin, plastic patch that you put on your skin. It releases female hormones into your body to protect against pregnancy.

Who should not use the hormonal skin patch?

You should not use the patch if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal skin patch?

You put a new patch on each week for 3 weeks. The fourth week is patch free, usually the time that you have a menstrual period. You place the hormonal skin patch where you can check it easily—on the upper outer arm, stomach, or upper body—but NOT on your breasts.

Reference ID: 3956479

Are you using the hormonal skin patch now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you have trouble remembering to change the patch each week? Has the patch ever come loose or fallen off and you did not immediately put on another one?
- Have you gained weight so that you weigh close to or more than 200 pounds?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using the hormonal skin patch, why do you think you would change to it?

Advantages

- It is not necessary to remember to take a daily pill.
- Many patients have more regular, lighter and shorter periods.

Disadvantages

- The patch does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If it becomes loose or falls off for more than 24 hours, you can get pregnant.
- If you leave the same patch on more than 1 week, you can get pregnant.
- Common side effects include breakthrough bleeding, nausea and vomiting, headaches and breast tenderness.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.
- Possible increased risk of blood clots. Please discuss this with your doctor.

Reference ID: 3956479

Hormonal Vaginal Ring

The hormonal vaginal ring is a small flexible ring that you put into your vagina once a month. It releases female hormones into your body and works like birth control pills.

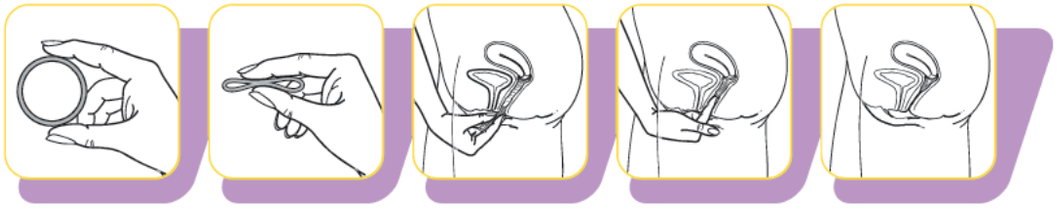
Who should not use the hormonal vaginal ring?

You should not use the hormonal vaginal ring if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal vaginal ring?

You put a new ring in your vagina once every 4 weeks on the same day of the week. You leave it there for 3 weeks and then take it out. During the one-week break, you usually have a menstrual period. **If the ring slips out of the vagina during the 3-week period, you must replace it within 3 hours.**



Are you using the hormonal vaginal ring now?

If you are, is this going to be your primary form of birth control?
Before you decide, ask yourself:

- Do you have trouble remembering to remove the ring after 3 weeks?
- Has the ring ever slipped out and you did not notice?
- Do you have trouble inserting the ring?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using a hormonal vaginal ring, why do you think you would change to it?

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Advantages

- It is not necessary to remember to take a daily pill.
- It does not need to be fitted by a doctor.
- Many female patients have more regular, lighter, and shorter menstrual periods.
- Your ability to have children returns quickly after stopping the ring.

Disadvantages

- The ring does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- You cannot use it with a diaphragm or cervical cap.
- Some medicines for a vaginal yeast infection increase the level of hormones released into the blood.
- You may have trouble inserting the ring.
- Pregnancy can happen if:
  - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
  - The ring slips out of the vagina and you do not replace it within 3 hours
  - The ring does not stay in the vagina for 3 weeks
  - You leave the ring in the vagina for more than 3 weeks
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.

Hormonal Shots—Single Hormone

Single hormonal shots use a progestin (a female hormone) to prevent pregnancy. They keep you from releasing eggs, keep eggs from growing in the uterus, and make it harder for sperm to get to an egg.

Who should not take single hormonal shots?

You should not take single hormonal shots if you have any unexplained vaginal bleeding, have or had breast cancer, have liver problems or are pregnant.

How do I take single hormonal shots?

Your dermatologist, gynecologist, or family doctor can give you a shot in your arm, belly, or buttocks once every 12 weeks.

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Are you taking single hormonal shots now?

- If yes, is this going to be your primary form of birth control? How often do you miss shots?
- If you are not getting single hormonal shots, why do you think you would change to them?

Advantages

- A single shot works for 12 weeks at a time.
- There is no daily pill to take.
- You can use it if you cannot take the hormone estrogen.

Disadvantages

- Single hormonal shots do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- They may cause thinning or loss of bone and should not be used for more than 2 years.
- They may cause irregular bleeding.
- If you are planning to get pregnant AFTER you finish your isotretinoin treatment, it may take up to 18 months to get pregnant after you stop getting single hormonal shots.

How soon does the single hormonal shot start to work?

If you get the shot within the first 5 days of your menstrual flow, the protection against pregnancy begins right away.

Hormonal Intrauterine Device

The hormonal IUD is a small piece of plastic your doctor puts into your uterus. The hormonal IUD has a progestin (female hormone) that keeps you from releasing eggs and slows down sperm.

Who should not use a hormonal IUD?

Some of the reasons women should not use the hormonal IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; problems with your immune system; leukemia; AIDS; IV drug abuse; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus.

Reference ID: 3956479

How do I use a hormonal IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The hormonal IUD can stay in place for up to 5 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Do you have a hormonal IUD now?

If you do, is this going to be your primary form of birth control? First, ask yourself these questions:

- Is the IUD in place? Can you feel the string?
- When did you last have it checked by your clinician? It needs to be checked within 3 months after you had it inserted.
- If you are not using a hormonal IUD, why do you think you would change to it?

Advantages

- It is a good choice for long-term birth control (5 years), and you may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps and heavy and longer menstrual periods for the first few months after it is placed, and increased chance of infection.
- Your body may push out the IUD. This can happen without your knowing it. This occurs mostly during a woman's menstrual period.
- You must check for the strings after each menstrual period to make sure the IUD is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Reference ID: 3956479

Ask yourself:

1. You have an IUD inserted as your choice for a primary form of birth control. Which of the following can you use as a second form?

   A) Male latex condoms with or without spermicide
   B) Hormonal shots
   C) Cervical cap without spermicide
   D) Diaphragm with spermicide
   E) Mini-pills (e.g., progesterone-only birth control pills)
   F) All of the above

Answer key: page 38

Hormonal Implants (Under-The-Skin)

Implantable birth control is a plastic rod(s), the size of a matchstick that is put under the skin in the upper arm by a healthcare provider in the office. It is effective for up to three years.

Who should not use

You should not use implantable birth control if you:

- Are pregnant
- Have or have had a current or past history of clots
- Have or have had liver disease
- Have or have had breast cancer
- Are allergic to anything in the implant

How do I use

The implant is put under the skin by a healthcare provider in the office. It generally cannot be seen once under the skin and once in, is effective for up to 3 years. It can be removed at any time by a procedure done by the healthcare provider in the office.

Advantages

- The rod works for up to 3 years
- There is no daily pill to take
- You can use it if you cannot take the hormone estrogen
- Your ability to have children may return quickly after removing the implant

Disadvantages

- Implant does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- May cause irregular and unpredictable bleeding
- Other side effects can include headache, acne, cramping and emotional changes

Reference ID: 3956479

- There can be side effects related to putting in the implant such as swelling, redness, pain, bruising, scarring, or infection
- There can be side effects related to removing the rod including a broken rod, or scar tissue making removal more difficult
- Rarely, it can be difficult or impossible to remove which may result in having to go to the operating room
- If you get pregnant, the chance of an ectopic pregnancy (a pregnancy not in your womb) is higher
- Ovarian cysts can occur
- May be less effective in women who are overweight or have liver problems –discuss this with your doctor
- Isotretinoin, antibiotics, and St. John's Wort may make the implant less effective

How soon does the implant work?

Discuss this with your healthcare provider.

Please make sure you can feel the implant rod under your skin after placement. If you cannot feel it, please do not start isotretinoin or have sexual intercourse until you talk to your healthcare provider.

Non-hormonal Intrauterine Device (Copper T IUD)

The Copper T IUD is a thin piece of plastic covered with the metal copper. It prevents pregnancy by slowing sperm down and keeping sperm from getting to the egg.

Who should not use the Copper T IUD?

Some of the reasons you should not use the Copper T IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus. You cannot use this IUD if you are allergic to copper or have Wilson's disease.

How do I use the Copper T IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The Copper T IUD can stay in place for up to 10 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Reference ID: 3956479

Advantages

- You can use it if you cannot take hormones.
- It is a good choice for long-term birth control (10 years).
- You may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps, heavy and longer menstrual periods.
- Your body may push out the IUD. This can happen without you knowing it. This occurs mostly during your menstrual period.
- You must check for the string to make sure it is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Tubal Sterilization (Tying Your Tubes)

Tubal sterilization (tying your tubes) is an operation that closes the tubes from the ovaries to the uterus so that the sperm cannot get through to the egg. Female sterilization may be accomplished using a variety of techniques. They are all considered to be very effective, virtually permanent methods of pregnancy prevention and, with the exception of hysteroscopic tubal sterilization, are immediately effective. Hysteroscopic tubal sterilizations are not effective immediately and require that a test be done in three months to confirm that the tubes are blocked. For the purposes of the iPLEDGE Program, hysteroscopic tubal sterilization is not considered an effective primary method of birth control unless the confirmation test has been performed.

Who should not have a tubal sterilization?

- You should not have a tubal sterilization if you ever want to get pregnant, at any time now or in the future.
- If you have already had a tubal sterilization, this is your primary form of birth control while taking isotretinoin. You must also choose either a secondary form of birth control or another primary form.
- If you are thinking about tubal sterilization, here is some information

Advantages

- It is very effective birth control.
- It works immediately after the surgery, with the exception of hysteroscopic tubal sterilization which requires that a test be done in three months to confirm that the tubes are blocked.

Reference ID: 3956479

Disadvantages

- Tubal sterilization does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If you want to have a child later, it is very difficult to re-open the tubes.
- It is surgery. You would need to have an operation.
- It increases the chance of ectopic pregnancy (pregnancy in the tubes) if sperm manage to get through the blocked tubes.

Partner's Vasectomy

A vasectomy is an operation that closes off the tubes that carry a man's sperm. The man's fluid should not have sperm in it after a vasectomy. If a man has sex before his doctor says his fluid has no sperm, the woman could get pregnant.

- If you have *only 1* partner *and* he has had a vasectomy, this can be your primary form of birth control while taking isotretinoin. You must also choose a second form of birth control. It is strongly recommended that you choose another primary form to give you very effective protection against getting pregnant.

If your partner is thinking about a vasectomy, here is some information about this very effective, but permanent, means of birth control.

Advantages

- It is very effective birth control.

Disadvantages

- A vasectomy does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If a male wants a child later, it is very difficult to open the tubes again.
- A vasectomy requires minor surgery.

Ask yourself:

- Is this my only sexual partner?

If you said no or if you are not sure, you cannot choose vasectomy as your primary form of birth control.

Reference ID: 3956479

SECONDARY FORMS OF BIRTH CONTROL

Secondary forms of birth control do not adequately protect against pregnancy if they are the only form used. However, they greatly increase your protection against getting pregnant if you use them along with a primary form every time you have sex. Effective secondary forms of birth control forms include barrier forms (male latex condoms, diaphragms, and cervical caps) and other forms (vaginal sponge). The diaphragm and cervical cap must always be used with a spermicide, and the male latex condom can be used with or without spermicide. The vaginal sponge contains spermicide. If a secondary form is your second form of birth control, you must use it every time you have sex with a male. The female condom is not an effective secondary form for the iPLEDGE Program.

Always use a spermicide with diaphragms and cervical caps.

Ask your doctor, gynecologist, or family doctor to show you how to use secondary forms. Be sure you know how to use them correctly.

Make sure you know exactly how to use these forms of birth control. Know what mistakes people make with secondary forms. These mistakes can get you pregnant.

Spermicides

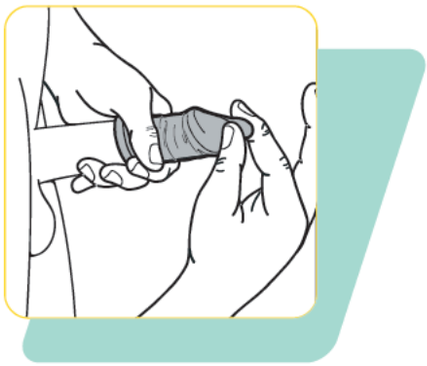
Spermicides come in several forms—creams, jellies, foams, and suppositories. You use spermicide 10 to 30 minutes before you have sex—each and every time—whenever the male comes in or near the female patient's vagina. Your dermatologist, gynecologist, family doctor, or birth control counselor can tell you how to use spermicides with your secondary barrier form.

Some people are allergic to spermicides. If you cannot use a spermicide, you must use 2 primary forms of birth control together, or a primary form with a male latex condom as your second form.

Male Latex Condom With or Without Spermicide

What is a male latex condom?

The male latex condom, also called a "rubber," is a thin cover put on the male's penis that traps sperm. You can use them with or without a spermicide .



How does my partner use it?

The male latex condom is unrolled on a male's erect penis as soon as he gets an erection. Waiting too long lets sperm leak out!

You can use a male latex condom with or without spermicide.

Reference ID: 3956479

A male latex condom is good for 1 time only. Do not let your partner try to use it more than once. Oils like petroleum jelly or baby oil can ruin a male latex condom. Safe lubricants include anything made with a water-based gel such as KY Jelly®.

Make sure the male latex condom stays on during sex. If it tears or comes off, call your doctor about emergency birth control.

Choosing a male latex condom as your secondary form

If you choose male latex condoms as a secondary form, your partner must be willing to use a male latex condom each and every time you have sex. Ask yourself:

- Does your sexual partner use a latex condom? Does he have a problem with using a latex condom each time you have sex?
- Does anyone ever force you to have sex if you do not want to?
- Have you and your partner ever forgotten to use latex condoms even when you had meant to?
- Have you ever had sex after drinking when you had not planned to?

  Alcohol and drugs can affect your judgment and decisions about having sex.

Male latex condoms may not be the best secondary form for you to choose if:

- Your partner does not want to use them
- You do not like to interrupt sex to let your partner put on a male latex condom
- You have had sex when you did not plan to and did not use birth control

You may want to choose a form you can control or one that you can insert before having sex.

Advantages

- Male latex condoms *do* protect against STIs (sexually transmitted infections) and HIV (AIDS).
- Male latex condoms are easy to buy, and no doctor's appointment or pelvic exam is needed.
- It is easy to tell when it breaks or slips.

Disadvantages

- Males and females can have a latex allergy.
- Male latex condoms can break or slip during sex.
- Many males do not like or want to use them. Your partner has to be committed to using male latex condoms. You are not in control of this birth control form.
- You must remember to use them every time.
- You must interrupt sex play to put on a male latex condom.

Reference ID: 3956479

How soon does a male latex condom work?

It works as soon as the male puts it on his erect penis.

Ask yourself:

- Will your partner actually use the latex condom?
- Did you talk with him about it?
- Did he agree?

1. Your partner says he is tired of using latex condoms and asks if he can skip it once in a while. Hormonal shots are your primary form of birth control. You should:

   A) Agree to let him just use a condom every other time you have sex

   B) Tell him to use latex condoms until you get a diaphragm to use

   C) Tell him that you will not have sex with him unless he uses a latex condom

   D) Not worry because you have not gotten pregnant yet

Answer key: page 38

Diaphragm And Spermicide

What is a diaphragm?

The diaphragm is a shallow latex cup edged with a flexible ring. It covers your cervix and keeps sperm from getting into your uterus. Your gynecologist or family doctor can fit you with one.

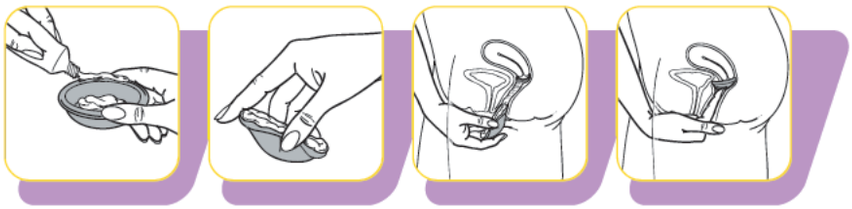
Who should not use the diaphragm?

You should not use a diaphragm if you have an allergy to latex or silicone, difficulty putting the diaphragm in, weak vaginal muscles, a history of bladder infections or toxic shock, or had a recent abortion.

Reference ID: 3956479

How do I use a diaphragm?

You bend the flexible ring and insert the diaphragm into your vagina. The back rim rests below and behind the cervix. The front rim is tucked behind your pubic bone. Before you insert it, you put spermicide in the center of the cup and around the ring.



You can put your diaphragm into the vagina up to 6 hours before sex. You have to leave it in place for at least 6 hours after you have sex. You must put spermicide in the vagina if you have sex again during this time. You should not leave it in for more than 24 hours at a time.

Choosing a diaphragm as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using diaphragms. If you are in one of these 2 groups, talk with your dermatologist, gynecologist, family doctor, or birth control counselor about whether the diaphragm is right for you.

Have you ever used a diaphragm? What do you like or dislike about the diaphragm?

- Do you find it easy to put it in?
- Have you been using spermicide with the diaphragm?
- Do you find it easy to remember to use it?
- Have you had your diaphragm checked by your gynecologist in the last 2 years to see if it still fits? You must have your diaphragm checked every 2 years, after a gain or loss of 10 pounds, OR after childbirth or an abortion.

If you answered yes to these questions, the diaphragm may be a good secondary form for you.

If you answered no to any of these questions, you should think about another secondary form.

Advantages

- You can easily carry a diaphragm with you and control its use.
- It is immediately effective.
- There are no hormones.
- You do not have to interrupt sex play—it can be inserted before sex.
- You can use it during your menstrual period.

Reference ID: 3956479

Disadvantages

- A diaphragm does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it hard to insert.
- You must put spermicide in your vagina if you have sex again.
- It can get pushed out of place during sex.
- It requires a prescription and pelvic exam. A diaphragm lasts about 1 to 2 years.
- You must check it for holes and tears and clean it after sex.

How soon does a diaphragm work?

It works as soon as spermicide is applied and you put it in correctly.

Cervical Cap And Spermicide

What is the cervical cap?

The cervical cap is a small latex or rubber cup. You use it with spermicide. It covers your cervix so that sperm cannot get in your uterus. It must fit perfectly to work. Your gynecologist or family doctor can fit you for one.

Who should not use a cervical cap?

You should not use a cervical cap if you have an allergy to latex or rubber, a history of pelvic infections, abnormal Pap tests, or Toxic Shock Syndrome (TSS).

How do I use a cervical cap?

The cap is filled one-third full with spermicide. You squeeze it as you put it in your vagina. You press it onto the cervix to cover it completely. You can put the cap in the vagina right before sex, but it stays better if you put it in place 30 minutes before sex. You have to leave it in place for at least 6 hours after you have sex. You can leave in place up to 48 hours.

The cervical cap is made of latex. Never use it with an oil-based lubricant like petroleum jelly. This will destroy the cap.

Reference ID: 3956479

What is the difference between a diaphragm and a cervical cap?

The cervical cap is a little harder to learn how to use. With a cervical cap, there is no need to insert extra spermicide if you have sex again. You can also leave the cap in place for a longer time—48 hours instead of 24 hours. You cannot use the cervical cap if there is any vaginal bleeding, such as during your menstrual period.

Choosing the cervical cap as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using the cervical cap. If you are in one of these 2 groups, talk with your gynecologist or family doctor about whether the cervical cap is right for you.

Have you ever used a cervical cap? What do you like or dislike about it?

- Do you find it easy to put in?
- Have you been using spermicide with the cervical cap?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the cervical cap may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Advantages

- You can easily carry a cervical cap with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance.

Disadvantages

- A cervical cap does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it harder to insert than a diaphragm.
- You cannot use it during your menstrual period.
- You need a prescription and a pelvic examination to fit a cervical cap.
- A cap lasts about 1 year.
- You must check it for holes and tears and clean it after sex.

Reference ID: 3956479

Vaginal Sponge

What is the vaginal sponge?

The vaginal sponge is a soft foam disc or pillow containing 1 gram of the spermicide nonoxynol-9. Inserting the sponge puts spermicide in your vagina and keeps it there during sex. You insert it in the vagina so it sits over your cervix. It has a string loop attached for easy removal.

Who should not use a vaginal sponge?

Female patients who are allergic to the spermicide nonoxynol-9 should not use the vaginal sponge.

How do I use the vaginal sponge?

First, wash your hands. Wet the sponge thoroughly with clean tap water. Squeeze the sponge gently several times until it is foamy. This releases the spermicide. Pinch the sides of the sponge together. Be sure the string loop is on the underside of the sponge. Squat or sit down, bend your wrist, and push the sponge gently up into your vagina as far as it will go. Check the position of the sponge to make sure the sponge covers your cervix.

How do I take the sponge out?

Wait at least 6 hours after your last sexual activity before taking the sponge out. You can leave it in place for up to 30 hours. You do not need more spermicide if you have sex more than once during that time. To take the sponge out, you need to catch the string loop and gently pull on it.

Choosing the vaginal sponge as your secondary form

Have you ever used a vaginal sponge? What do you like or dislike about it?

- Do you find it easy to put in? Easy to take out?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the vaginal sponge may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Reference ID: 3956479

Advantages

- You can easily carry a vaginal sponge with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance and is effective for up to 30 hours.
- No fitting is needed; you can buy it over the counter.
- It is comfortable and easy to use.

Disadvantages

- The vaginal sponge does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- It is not as effective in female patients who have had children.

EMERGENCY BIRTH CONTROL (Emergency Contraception)

Emergency birth control is also called "after sex" or "morning after" birth control. It can prevent pregnancy after sex without adequate protection. Emergency birth control prevents release of the egg, joining of the sperm and the egg, or implanting of the egg in the uterus. Emergency birth control is only for a female patient who is sure she is not already pregnant.

There are 2 forms of emergency birth control:

1. Emergency Contraceptive Pills (ECPs)—some must be used within 3 days, others must be used within 5 days of having sex without adequate protection. The sooner you take ECP, the more likely it is to work. It is best if ECP begins within 12 hours after you have sex without adequate protection. The pills may give you severe nausea. Ask your doctor for something to help with the nausea if you need this treatment. ECP does not take the place of your usual birth control, nor does it continue to prevent pregnancy during the rest of your menstrual cycle.

2. Putting in an IUD—used within 5 days. You need to have the IUD inserted within 5 days of having sex without adequate protection.

When would I need emergency birth control?

Call your doctor or gynecologist about emergency birth control if you had sex without adequate protection, such as:

- You forgot to take 2 or more birth control pills and had sex.
- You had sex without using a second form of birth control.
- You were late for your birth control hormonal shot and had sex.
- Your partner's condom broke or slipped off.
- Your diaphragm or cervical cap slipped out of place or ripped during sex.

Reference ID: 3956479

Emergency birth control is meant only for emergencies. It does NOT take the place of your usual 2 forms of birth control and it will not protect against sexually transmitted infections (STIs). Emergency birth control is not to be used instead of regular birth control and it does not work if you are already pregnant.

Where can I get emergency birth control?

You can get emergency birth control from:

- Private doctors or nurse practitioners
- Planned Parenthood
- Women's health centers
- Many hospital emergency rooms (unless they are owned by organizations opposing birth control)
- Available over-the-counter

Whom should I call if I cannot find emergency birth control?

Call the private toll-free Emergency Contraception Hotline at 1-888-NOT-2-LATE (1- 888-668-2528). They will ask for your city or ZIP code to help you find emergency birth control near you.

Ask yourself:

1. The right way to use emergency birth control is:
   - A) As a second form of birth control
   - B) If you find a tear in your cervical cap after sex
   - C) If you missed several birth control pills and then have sex
   - D) Only after a positive pregnancy test

Answer key: page 38.

REASONS FEMALE PATIENTS GET PREGNANT

There are many reasons female patients get pregnant when they do not want to. You can avoid most of these.

- They did not avoid sex with a male when they were not using birth control.
- They used a birth control form that did not work very well.
- They did not use birth control all the time and every time they had sex.
- They did not use their birth control the right way.
- They had sex with a male partner when they were not expecting to.
- Their birth control form failed.

For most of the reasons, you can make a choice not to make the same mistake. It is very important that you are careful about birth control. Use your birth control as the iPLEDGE Program requires. Do not make mistakes that can lead to unexpected pregnancy.

Reference ID: 3956479

SEPARATING THE MYTHS FROM THE FACTS

Myths are ideas that many people believe are true, but they are not true. You need to know the facts about sex, birth control, and pregnancy to protect yourself.

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
You cannot get pregnant the first time you have sex.	You can get pregnant **any** time you have sex.
You cannot get pregnant if you "do it" standing up.	You can get pregnant in any position.
You will not get pregnant if you do not have an orgasm (come).	You can get pregnant any time you have sex regardless of whether or not you have an orgasm.
Douching keeps you from getting pregnant.	Douching does **not** prevent pregnancy.
You do not have to use something every time.	You should use birth control every time you have sex.
You will not get pregnant if it is the "safe time" of the month.	There is no safe time, even for female patients who are regular with their menstrual periods. Your body can change and you could get pregnant.
You will not get pregnant if he pulls out before he comes.	Even if he pulls out, he may leak sperm before he comes and you can get pregnant.
It is safe for me to have sex any time, unless I feel PMS changes or pain near my ovaries.	You can get pregnant any time you have sex, not just when you think you are ovulating (releasing an egg).
You cannot get pregnant if you have not had a menstrual period yet.	Your ovaries release an egg (ovulation) before your first menstrual period. You can get pregnant even the very first time this happens, if you have been having sex.
You cannot get pregnant if you have sex underwater.	You can get pregnant **anywhere** you have sex.

Reference ID: 3956479

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
My partner says he is sterile (has no sperm) because he had mumps. He never got anyone else pregnant, so I will not get pregnant.	Mumps rarely causes sterility (no sperm). You can get pregnant if you have sex with a man who has had mumps.
You cannot get pregnant if you miss only 1 birth control pill.	Birth control pills work best when you take them as prescribed. You can get pregnant if you miss even one pill, especially at the beginning of your pill cycle
Sexually active means you have to move during sex. If I do not move, I cannot get pregnant.	You can get pregnant any time you have sex, whether you move or lie still.
I am going through menopause and only get my menstrual period every couple of months.	You can get pregnant until you have missed your menstrual period for 1 year—12 months in a row.

You may have heard or read about something that is not listed here that you think might keep you from getting pregnant. Be sure to ask your dermatologist, gynecologist, or family doctor about any form that you cannot find in this book that you think, or have heard, will keep you from getting pregnant. You can only use the effective forms of birth control for the iPLEDGE Program.

SEX, ALCOHOL, AND DRUGS

You have seen this message many times before. Alcohol and drugs can make you unable to use good judgment. While you are taking isotretinoin and for 1 month after your last dose, you need to be able to remember to use 2 effective forms of birth control together each and every time you have sex with a male.

Do not let drugs or alcohol keep you from using your secondary form when you have sex. Use it the right way. You need to be in control of yourself so:

- You use your secondary form, OR you get your partner to use a male latex condom with or without spermicide
- You use a vaginal sponge, or a diaphragm or a cervical cap with spermicide

Reference ID: 3956479

RECOGNIZING PREGNANCY

If you think you might be pregnant, stop isotretinoin and call your doctor right away. Here are some signs that you might be pregnant:

- You miss your menstrual period.
- You have nausea first thing in the morning.
- Your breasts feel really tender, like at the beginning of a menstrual period.
- The area around your nipples may look darker.
- You feel really tired and want to sleep.
- You feel you have to go to the bathroom a lot.
- You may have spotting of blood at the time of your menstrual period, but no real bleeding.

Ectopic (Tubal) Pregnancy

Sometimes a baby starts to grow outside the uterus. This is a serious problem. Call your doctor right away, if you have these signs:

- Sudden pain or severe cramping in your lower abdomen
- Bleeding or spotting with abdominal pain after you miss a menstrual period
- Fainting or dizziness lasting more than a few seconds

Pregnancy Testing

If you have any questions about whether you might be pregnant, talk with your doctor.

Reference ID: 3956479

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Reference ID: 3956479

Birth Control Information

You can get information about birth control 24 hours a day, 7 days a week on the telephone. Call the toll-free number **1-866-495-0654** to learn about these subjects:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

This telephone line is for education only. It does not take the place of talking with your doctor. He or she is the best source of information for you.

Answer Key To Birth Control Questions

Page 8:
- 1. B
- 2. A and D

Page 11:
- 1. B
- 2. B and C
- 3. A

Page 14:
- 1. B
- 2. C

Page 20:
- 1. A and D

Page 26:
- 1. B and C

Page 32:
- 1. B and C

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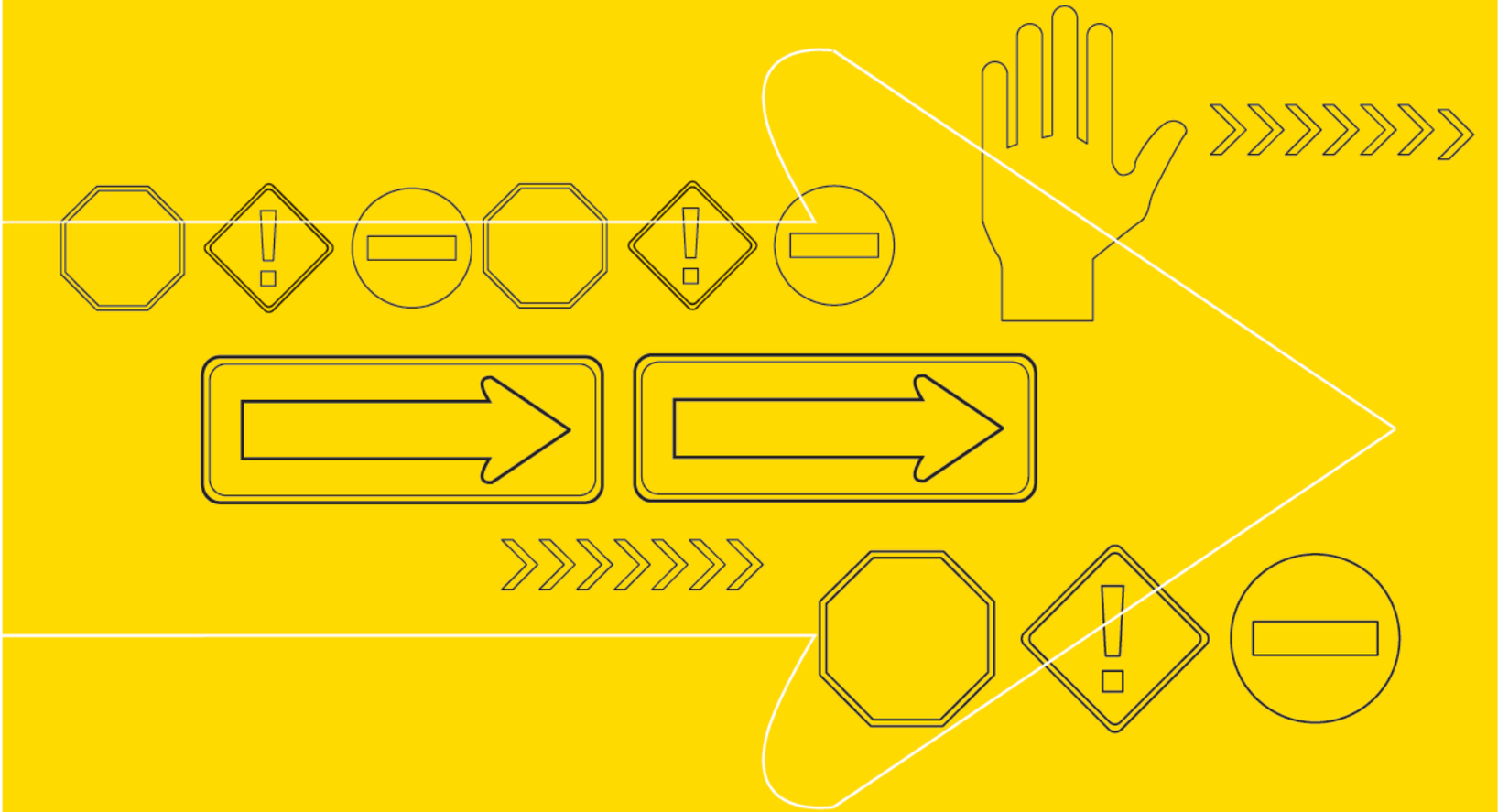

www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™
Committed to Pregnancy Prevention

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Most Recent Modification: July 2016

The iPLEDGE Program

Contraception Referral Form And Contraception Counseling Guide

Referral form for contraception counseling and guide for counselors to effective forms of contraception

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Contraception Referral Form And Contraception Counseling Guide

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About This Referral Form

The Isotretinoin Contraception Referral Form, brought in to you by this patient, has been filled out in part by the prescriber. Please fill out the rest of the form at the conclusion of your counseling session and fax or mail the copy back to the prescriber, keeping a copy for your own records.

On the back of the referral form is a reimbursement form for contraceptive counseling services. The iPLEDGE Program provides reimbursement for 1 contraception counseling session for patients who have been prescribed isotretinoin. Please complete the form and fax it to 1-866-495-0660.

Reference ID: 3956479

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Phoenix, AZ 85038

ISOTRETINOIN CONTRACEPTION REFERRAL FORM

Prescriber: Complete for Patients Being Referred for Contraception Counseling

Patient_____, iPLEDGE Program ID#_____ is considering treatment with isotretinoin. I am referring her for counseling to help her choose her 2 forms of contraception before she receives her first prescription.

Please complete the Record of Contraception Counseling below and return this form to my office, via fax or mail.

She had a negative (serum/urine) pregnancy test on _____

Please review this *Contraception Counseling Guide* for details on the iPLEDGE Program contraception requirements.

Isotretinoin Prescriber's Name_____

Address _____

Telephone _____-_____-_____ Fax _____-_____-_____

Isotretinoin Prescriber's Signature _____

Date _____

RECORD OF CONTRACEPTION COUNSELING

Contraception Counselor: Complete Form and Fax or Mail Back to Isotretinoin Prescriber

I have provided the following for your patient _____

- ❑ Comprehensive contraception counseling
- ❑ Information about emergency contraception

The patient has:

- ❑ Not yet decided upon the forms of contraception she will use
- ❑ Chosen 2 forms of contraception
- ❑ Decided to abstain from any sexual contact with a male and is not planning to use 2 forms of contraception. I informed her that abstinence without using contraception is not recommended for the iPLEDGE Program for sexually active women.

Primary Form _____

Secondary or Second Primary Form_____

I have prescribed the selected contraception.

❑ Yes ❑ No (Please comment below)

I believe that this patient is fully committed to complying with the contraceptive requirements of the iPLEDGE Program.

❑ Yes ❑ No (Please comment below)

_____

Name_____

Address _____

Telephone _____

Specialty (circle one): OB-GYN Fam Prac IM RN LPN Other_____

Contraception Counselor's Signature _____

Date _____

Prescriber Copy-White **Contraception Counselor Copy-Yellow** **Patient Copy-Pink**

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Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

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FAXABLE REIMBURSEMENT FORM

The Following Restrictions Apply:

Only consulting clinicians who provide initial pregnancy prevention counseling are eligible for reimbursement for such counseling. Other services provided during this visit are not eligible for reimbursement. The physician prescribing isotretinoin, or any other person working under the direct supervision of said physician, is not eligible for this reimbursement provision. The reimbursement fee is up to $150.00, which has been determined to be an average, usual, and customary reimbursement for service of this type. Information will be used only for reimbursement; the isotretinoin manufacturers will not use it for any other purpose.

Reimbursement For Pregnancy Prevention Counseling

To receive reimbursement for providing pregnancy prevention counseling to an isotretinoin patient, please answer the following questions, and sign, date, and send the completed form via fax to: 1-866-495-0660.

Contraception Counselor Name_____

Payee Name (if different than Contraceptive Counselor) _____

Office Telephone Number _____-_____-_____ Tax ID Number_____

Payee Address_____

City_____ State _____ ZIP _____

Name of Referring Physician _____

Office Telephone Number_____-_____-_____-_____

City_____ State _____ ZIP _____

Patient's Name _____

Patient's iPLEDGE Program ID Number _____

- ❑ I have provided pregnancy prevention counseling to this patient. I have mailed or faxed the record of pregnancy prevention counseling (on reverse side) to the isotretinoin prescriber.
- ❑ I am not the prescribing physician of isotretinoin to the patient referenced above, nor am I employed by said prescribing physician.
- ❑ I have not, and will not, bill or submit for reimbursement either directly or indirectly, under Medicaid, Medicare, or similar federal or state healthcare programs, or under any private insurance, HMO, or other healthcare benefit program for the pregnancy prevention counseling services described above.
- ❑ I attest that all of the above information is accurate and understand that I must check each box above to receive reimbursement.
- ❑ I have included a signed W-9 Form, or already have a W-9 form on file for payment from the iPLEDGE Program. A blank W-9 form and instructions for completion can be found at www.irs.gov

Signature _____ Date _____

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Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

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CONTRACEPTION COUNSELING FOR ISOTRETINOIN PATIENTS

Isotretinoin is used to treat severe recalcitrant nodular acne; however, it is also a known human teratogen. Over one third of all babies exposed to isotretinoin *in utero* and carried to term have major birth defects.[1,2] The public health goal for isotretinoin is to eliminate fetal exposure by ensuring that no female starts isotretinoin therapy if pregnant and no female on isotretinoin therapy becomes pregnant. The US Food and Drug Administration has approved the iPLEDGE Program, an enhanced pregnancy risk management program for isotretinoin, to help achieve that end.

The contraception that a patient selects can have a dramatic effect on her chance of becoming pregnant. A patient using isotretinoin needs to select forms with low failure rates that she and/or her partner will use correctly each time they have intercourse.

Your Role

This patient is being referred to you because she has asked for counseling to help her comply with the contraception requirements of the iPLEDGE Program.

The patient must select and commit to using 2 forms of effective contraception simultaneously, at least 1 of which must be a primary form, unless the patient commits to continuous abstinence from heterosexual contact, or the patient has undergone a hysterectomy or bilateral oophorectomy, or has been medically confirmed to be post-menopausal. She must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin therapy, during isotretinoin therapy, and for 1 month after discontinuing isotretinoin therapy.

It is strongly recommended that a patient use a primary form of contraception and is committed to using a second form as well, even if she says she will be abstinent for the entire required period. Isotretinoin is not recommended for sexually active females of reproductive potential whom you believe will not be able to maintain abstinence or will not use contraception, as the program requires.

Please read this iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide completely before you begin your counseling session. It provides a pregnancy risk management context through which contraception choices for female patients taking isotretinoin can be viewed. It does not contain detailed information on the various forms of contraception.

The iPLEDGE Program Birth Control Workbook, which is for patients, contains more information on effective primary and secondary forms of contraception. It is not complete information on any of the forms, and the patient is encouraged to ask questions about specific forms or issues. The workbook has questions on such issues as medication adherence and lifestyle choices for the patient to think about in choosing contraception. Please review her responses with her.

Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Reference ID: 3956479

COUNSELING GOALS

Ensure That The Patient:

- Understands the risk of having a child with significant birth defects from exposure to isotretinoin.
- Understands the need for using 2 forms of contraception together consistently and correctly and knows when to contact her prescriber for emergency contraception.
- Chooses the forms of contraception that will work best for her, that will provide her with the lowest practical failure rate, and that she and her partner will actually use. Adherence impacts the failure rate of hormonal combination oral contraceptives more strongly than other primary forms. (Please see "Hormonal Combination Oral Contraceptives As A Primary Form" on page 6.)
- Commits fully to not becoming pregnant and to using 2 forms of contraception simultaneously, consistently, and correctly. In previous isotretinoin risk management programs, patients understood the need for 2 forms of contraception; however, they did not comply, despite adequate information about the risk to the fetus. If, after counseling, the patient recognizes she will not be able to commit fully, encourage her to not take isotretinoin or do not prescribe.
- Is able and willing to maintain abstinence, if that is her choice after counseling. If a patient who has ever been sexually active chooses abstinence, and you believe that she will not be able to maintain abstinence and will not use contraception, encourage her to not take isotretinoin.

Counseling younger teens

For younger teens, it is important to stress the following aspects of contraception for the iPLEDGE Program during counseling:

- The birth control forms that are effective as primary and secondary forms.
- Why it is important to use 2 forms of birth control. Younger teens may need more emphasis on this point to fully understand it and comply.
- Emergency contraception. Younger teens may need more explanation from you about the need to take immediate action if they had unprotected sex.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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CONTRACEPTION REQUIREMENTS

Using 2 Forms Of Contraception Provides More Protection

Use of 2 forms of contraception (at least one of which is a primary form) simultaneously substantially reduces the chances that a female will become pregnant over the risk of pregnancy with either form alone.

In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin.[3] Because of this possibility and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE Program requires the additional protection of a second form of contraception.

Selecting An Effective Primary Form Of Contraception

Table 1 on the next page lists, by typical use failure rate, the primary forms of contraception acceptable in the iPLEDGE Program. The single most important decision in contraception for the iPLEDGE Program is selecting a primary form with a very low failure rate that the patient can and will use as perfectly as possible. Other important factors to consider in selecting a primary form include side effects, contraindications, and willingness and ability to use it perfectly. All of these factors influence compliance and the chance of unwanted pregnancy.

Hormonal Combination Oral Contraceptives As A Primary Form

If the patient is currently taking or planning to take oral contraceptives, review that section in *The iPLEDGE Program Birth Control Workbook* with her. Her answers to questions on consistency and medication adherence will provide insight into potential issues with iPLEDGE Program adherence.

Other contraception not requiring daily choices may be a better choice for a patient who does not take oral contraceptives perfectly. For example, if such a patient chooses an IUD, she reduces her chances of becoming pregnant by up to approximately 90%.[3] It is critical that such a patient choose a form other than oral contraceptive agents.

Table 1: Primary Forms Of Contraception By Typical Use Failure Rate

	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	**Perfect Use**	**Typical Use**
Hormonal Implantable	0.05%	0.05%
Partner's Vasectomy	0.10%	0.15%
Hormonal IUD (LNg20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A)[b]	0.60%	0.80%
Hormonal Injectable (single)	0.30%	3.00%
Hormonal Transdermal Patch	0.30%	8.00%
Hormonal Vaginal Ring	0.30%	8.00%
Hormonal Combination Oral Contraceptives[b]	0.30%	8.00%

a. Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Stewart F, et al, eds. *Contraceptive Technology*. Nineteenth Revised Edition, New York, NY: Ardent Media 2007.
b. The IUD Progesterone T and progestin-only "mini-pills" are not acceptable primary forms for the iPLEDGE program. (See "Unacceptable Forms Of Contraception" on page 8.)

Selecting An Effective Secondary Form Of Contraception

Table 2 lists the acceptable secondary forms of contraception in the iPLEDGE Program. There are 2 forms of secondary contraception: barrier and other. Barrier forms include the diaphragm and cervical cap (both of which must be used with spermicide) and the male latex condom (which can be used with or without spermicide). The other form is the vaginal sponge, which contains spermicide. The most important issue for a secondary form is whether it will be used each time the patient has intercourse (i.e., will it be in place when the first form fails). Failure rate with perfect use is of secondary importance.

Help the patient select a secondary form that she and/or her partner can fully commit to using correctly each time they have intercourse. If it is apparent that more than 1 of the forms would be equally suited, select the form with the lower or lowest perfect use failure rate, as this will reduce the overall likelihood of becoming pregnant.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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Table 2: Secondary Forms Of Contraception Listed By Typical Use Failure Rate		
	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	Perfect Use	Typical Use
Barrier Forms		
Male Latex Condom[b]	2%	15%
Diaphragm[*]	6%	16%
Cervical Cap[d,*]	9%	20%
Other Forms		
Vaginal Sponge[c]	9%	16%

a. Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Stewart F, et al, eds. *Contraceptive Technology*. 19th Revised Edition, New York, NY: Ardent Media, 2007

b. Female condoms are not acceptable for the iPLEDGE program. (See "Unacceptable Forms Of Contraception" below.) Failure rate for Male Latex Condom is for use without spermicide.

c. Failure rate for nulliparous women; rate is approximately double for parous women.

d. Adapted from Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Stewart F, et al,eds. *Contraceptive Technology*. 17th Edition, New York, NY: Irvington Publishers 1998.

* Failure rates for Diaphragm and Cervical Cap include the use of spermicide.

UNACCEPTABLE FORMS OF CONTRACEPTION

The following forms of contraception are not acceptable for the iPLEDGE Program:

- Progesterone-only "mini-pills"
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix‡

Patients currently using these forms of contraception must switch to effective forms of contraception. They must use 2 effective forms together (at least one of which must be a primary form) consistently and correctly for at least 1 month and have a negative pregnancy test before beginning isotretinoin.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479

EMERGENCY CONTRACEPTION

Review this section in *The iPLEDGE Program Birth Control Workbook* with the patient. She should know when to call her prescriber for possible emergency contraception. She should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms she selected.

ABSTINENCE

For this program, all females of reproductive potential must fully commit to pregnancy prevention. Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE Program who are or have been sexually active. Abstinence may be appropriate when it is a lifestyle choice, such as religious practice, and not just a social circumstance, such as not having a current partner. If, after counseling, a sexually active patient chooses abstinence without contraception, she must understand that isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program.

REFERENCES

1.Lammer EJ, Chen DT, Hoar RM, et al. Retinoic acid embryopthy. *N Engl J Med*. 1985;313:837-841.
2.Gideon K, Avner M, Shear N. Generic isotretinoin: a new risk for unborn children. *CMAJ*. 2004;170:1567-1568.
3.Isotretinoin Prescribing Information, 2005.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

Reference ID: 3956479

Reporting a Pregnancy

If you become aware of a pregnancy in a patient taking isotretinoin, please report the pregnancy to the iPLEDGE Program by calling **1-866-495-0654** and choosing the option to "Report a Pregnancy."

Please also remind any patient who is pregnant to contact the doctor who prescribed her isotretinoin.

Please see accompanying complete product information, including boxed **CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS,** and **ADVERSE REACTIONS.**

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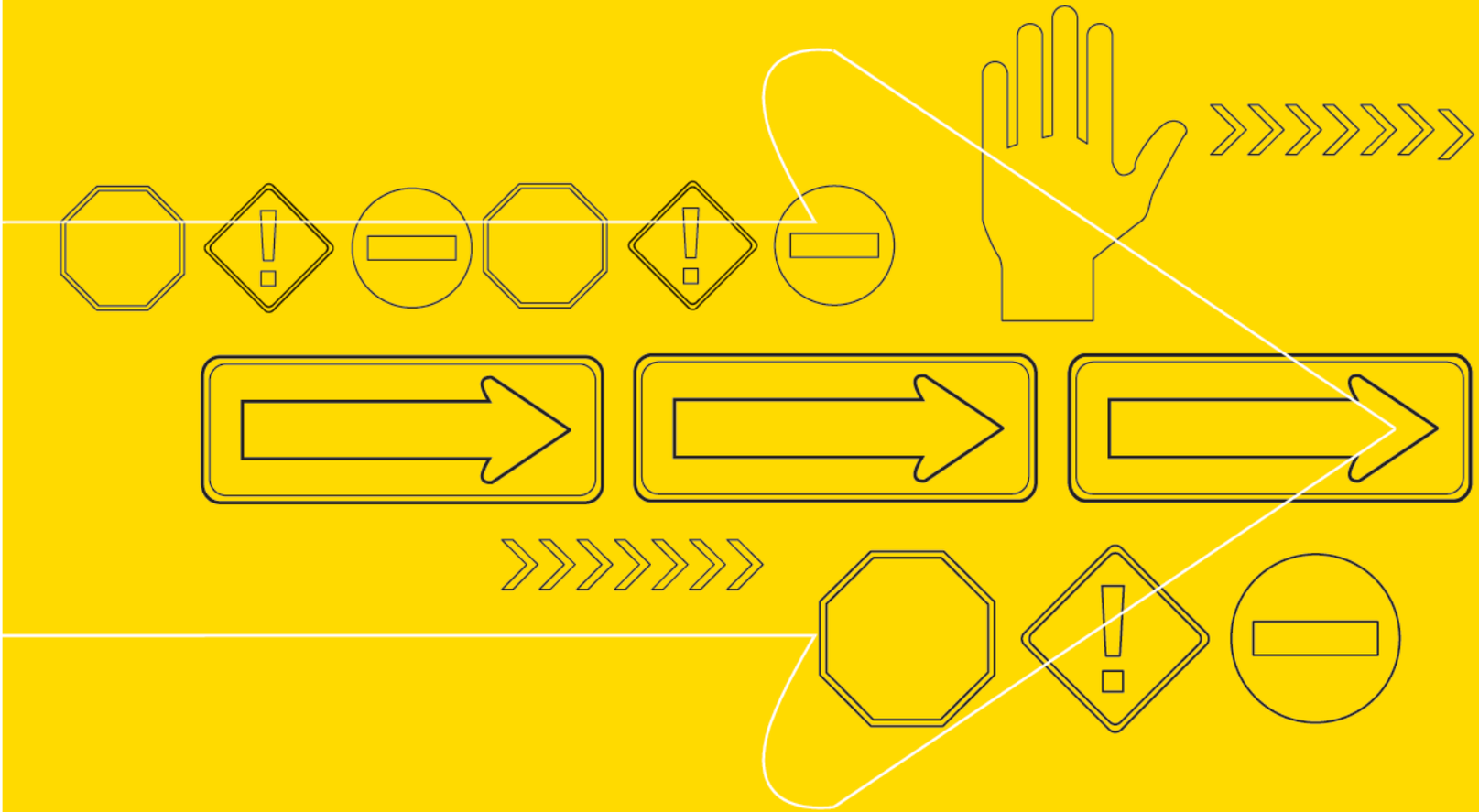

www.ipledgeprogram.com 1-866-495-0654

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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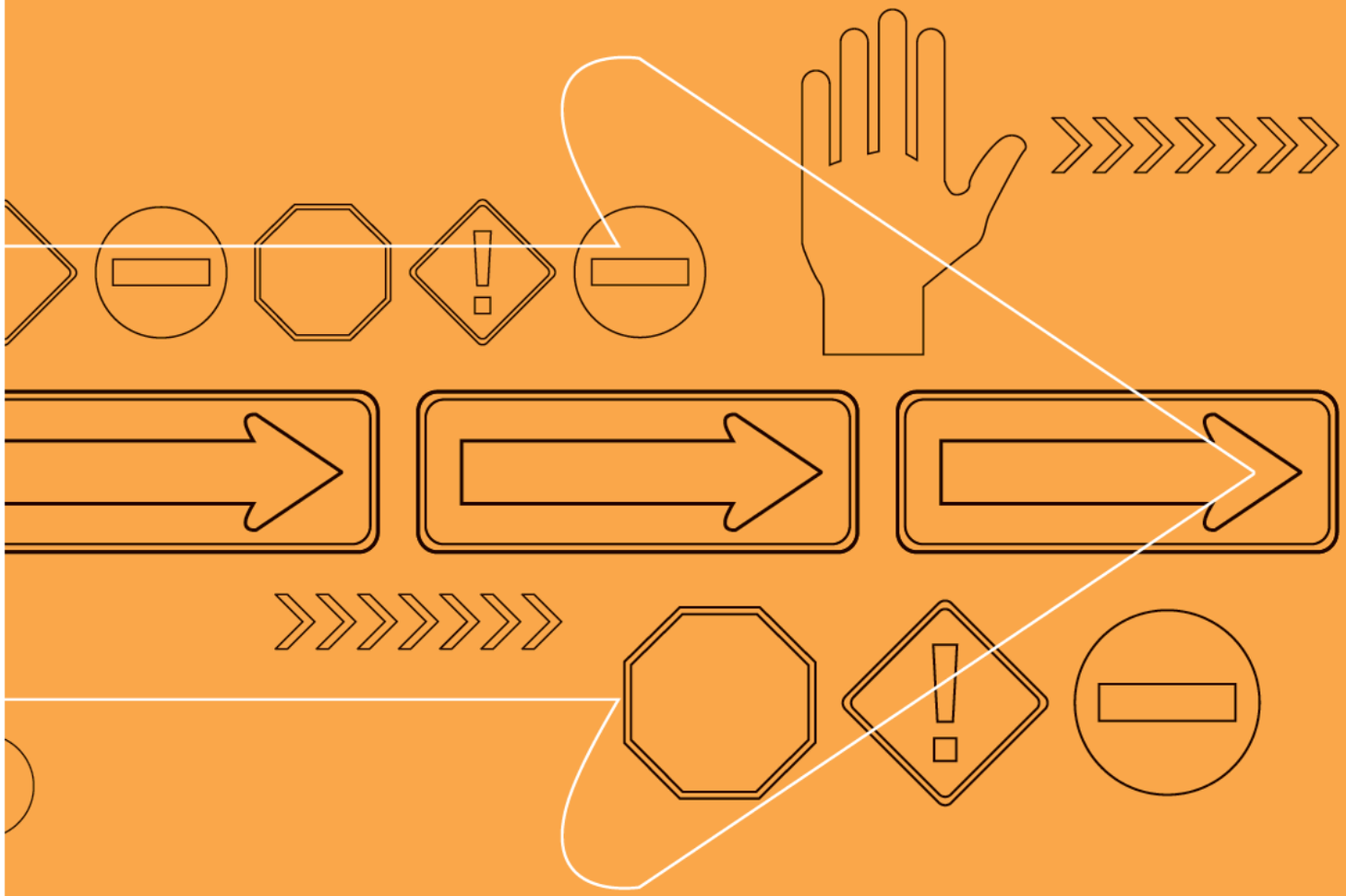
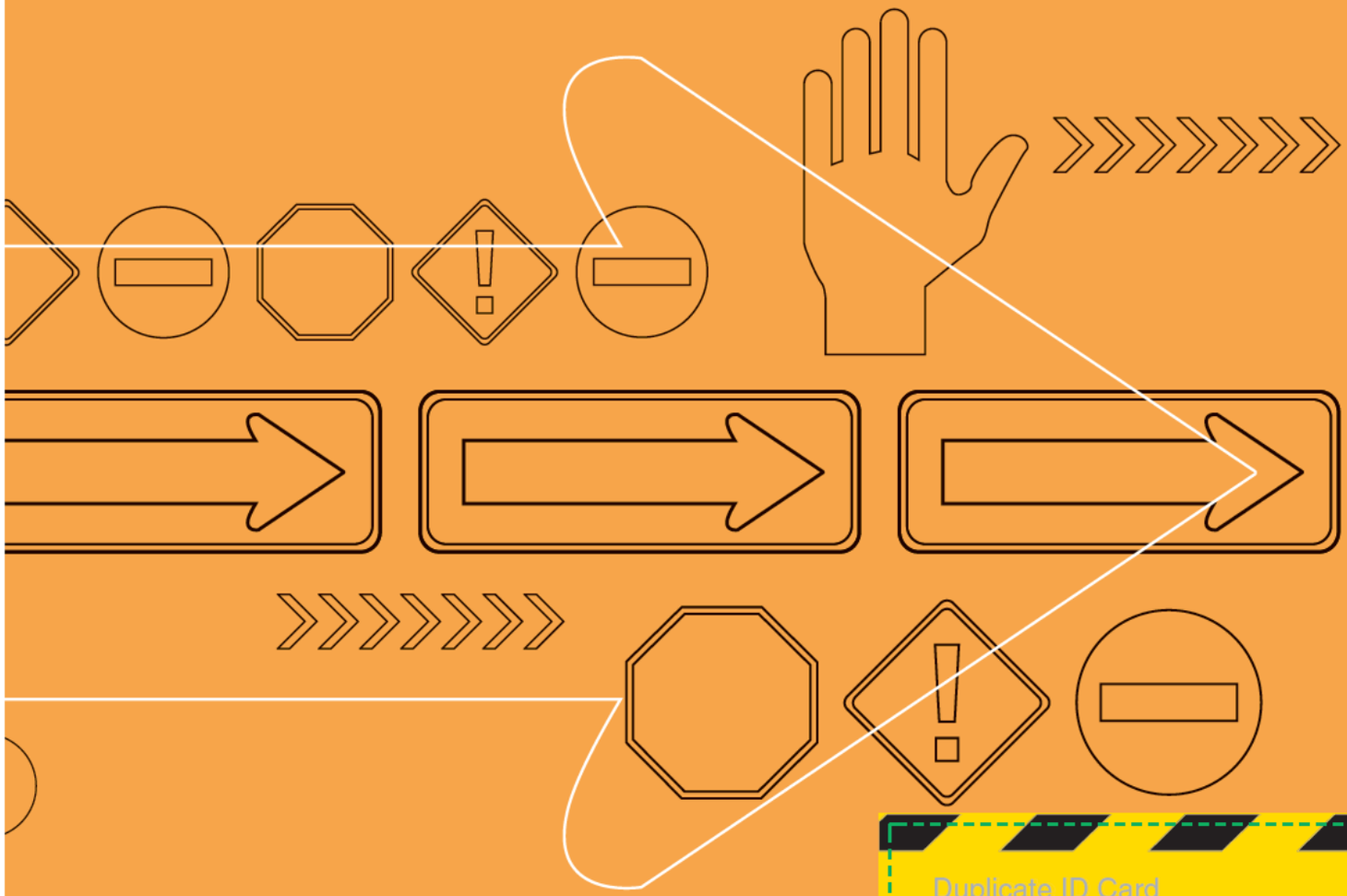


The card you need to take with you to doctor visits and to the pharmacy while on isotretinoin



Peel off sticker for patient's file

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your 7-day window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for Important safety Information

iPLEDGE™ Committed to Pregnancy Prevention

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
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- Visit your doctor monthly
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  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your 7-day window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for Important safety Information

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Stop isotretinoin and call your doctor right away if you are pregnant.
Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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Patient Information/Informed Consent (for all patients):

To be completed by patient (and parent or guardian if patient is under age 18) and signed by the doctor.

Read each item below and initial in the space provided if you understand each item and agree to follow your doctor's instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not take isotretinoin if there is anything that you do not understand about all the information you have received about using isotretinoin.

1. I, _____
(Patient's Name)

   understand that isotretinoin is a medicine used to treat severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, severe nodular acne can lead to permanent scars.

   Initials: _____

2. My doctor has told me about my choices for treating my acne.

   Initials: _____

3. I understand that there are serious side effects that may happen while I am taking isotretinoin. These have been explained to me. These side effects include serious birth defects in babies of pregnant patients. [Note: There is a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)].

   Initials: _____

4. I understand that some patients, while taking isotretinoin or soon after stopping isotretinoin, have become depressed or developed other serious mental problems. Symptoms of depression include sad, "anxious" or empty mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent. No one knows if isotretinoin caused these behaviors or if they would have happened even if the person did not take isotretinoin. Some people have had other signs of depression while taking isotretinoin (see #7).

   Initials: _____

5. Before I start taking isotretinoin, I agree to tell my doctor if I have **ever** had symptoms of depression (see #7), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems. Being psychotic means having a loss of contact with reality, such as hearing voices or seeing things that are not there.

   Initials: _____

6. Before I start taking isotretinoin, I agree to tell my doctor if, to the best of my knowledge, anyone in my family has ever had symptoms of depression, been psychotic, attempted suicide, or had any other serious mental problems.

   Initials: _____

7. Once I start taking isotretinoin, I agree to stop using isotretinoin and tell my doctor right away if any of the following signs and symptoms of depression or psychosis happen. I:
   - Start to feel sad or have crying spells
   - Lose interest in activities I once enjoyed
   - Sleep too much or have trouble sleeping
   - Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
   - Have a change in my appetite or body weight
   - Have trouble concentrating
   - Withdraw from my friends or family
   - Feel like I have no energy
   - Have feelings of worthlessness or guilt
   - Start having thoughts about hurting myself or taking my own life (suicidal thoughts)
   - Start acting on dangerous impulses
   - Start seeing or hearing things that are not real

   Initials: _____

8. **I agree to return to see my doctor every month I take isotretinoin to get a new prescription for isotretinoin, to check my progress, and to check for signs of side effects.**

   Initials: _____

9. Isotretinoin will be prescribed just for me — I will not share isotretinoin with other people because it may cause serious side effects, including birth defects.

   Initials: _____

10. I will not give blood while taking isotretinoin or for 1 month after I stop taking isotretinoin. I understand that if someone who is pregnant gets my donated blood, her baby may be exposed to isotretinoin and may be born with serious birth defects.

    Initials: _____

11. I have read *The iPLEDGE Program Patient Introductory Brochure* and other materials my provider provided me containing important safety information about isotretinoin. I understand all the information I received.

    Initials: _____

12. My doctor and I have decided I should take isotretinoin. I understand that I must be qualified in the iPLEDGE Program to have my prescription filled each month. I understand that I can stop taking isotretinoin at any time. I agree to tell my doctor if I stop taking isotretinoin.

    Initials: _____

I now allow my doctor _____ to begin my treatment with isotretinoin.

Patient Signature: _____ Date: _____

Parent/Guardian Signature (if under age 18): _____ Date: _____

Patient Name (print) _____

Patient Address _____ Telephone_____ – _____ – _____

I have:

- fully explained to the patient, _____, the nature and purpose of isotretinoin treatment, including its benefits and risks
- provided the patient the appropriate educational materials, *The iPLEDGE Program Patient Introductory Brochure* and asked the patient if he/she has any questions regarding his/her treatment with isotretinoin
- answered those questions to the best of my ability

Doctor Signature: _____ Date: _____

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

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Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)

To be completed by the patient (and her parent or guardian* if patient is under age 18) and signed by her doctor.

Read each item below and initial in the space provided to show that you understand each item and agree to follow your doctor's instructions. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

*A parent or guardian of a minor patient (under age 18) must also read and initial each item before signing the consent.

_____
(Patient's Name)

1. I understand that there is a very high chance that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking isotretinoin. This can happen with any amount and even if taken for short periods of time. This is why I must not be pregnant while taking isotretinoin.
   Initial: _____
2. I understand that I must not get pregnant 1 month before, during the entire time of my treatment, and for 1 month after the end of my treatment with isotretinoin.
   Initial: _____
3. I understand that I must avoid sexual intercourse completely, or I must use 2 separate, effective forms of birth control (contraception) **at the same time**. The only exceptions are if I have had surgery to remove the uterus (a hysterectomy) or both of my ovaries (bilateral oophorectomy), or my doctor has medically confirmed that I am post-menopausal.
   Initial: _____
4. I understand that hormonal birth control products are among the most effective forms of birth control. Combination birth control pills and other hormonal products include skin patches, shots, under-the-skin implants, vaginal rings, and intrauterine devices (IUDs). Any form of birth control can fail. That is why I must use 2 different birth control methods at the same time, starting 1 month before, during, and for 1 month after stopping therapy every time I have sexual intercourse, even if 1 of the methods I choose is hormonal birth control.
   Initial: _____
5. I understand that the following are effective forms of birth control:

Primary forms	Secondary forms
• tubal sterilization (tying your tubes) • partner's vasectomy • intrauterine device • hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)	*Barrier forms* • male latex condom with or without spermicide • diaphragm with spermicide • cervical cap with spermicide *Others:* • vaginal sponge (contains spermicide)

   A diaphragm and cervical cap must each be used with spermicide, a special cream that kills sperm

   I understand that at least 1 of my 2 forms of birth control must be a primary method.
   Initial: _____
6. I will talk with my doctor about any medicines including herbal products I plan to take during my isotretinoin treatment because hormonal birth control methods may not work if I am taking certain medicines or herbal products.
   Initial: _____
7. I may receive a free birth control counseling session from a doctor or other family planning expert. My isotretinoin doctor can give me an isotretinoin Patient Referral Form for this free consultation.
   Initial: _____
8. I must begin using the birth control methods I have chosen as described above at least 1 month before I start taking isotretinoin.
   Initial: _____
9. I cannot get my first prescription for isotretinoin unless my doctor has told me that I have 2 negative pregnancy test results. The first pregnancy test should be done when my doctor decides to prescribe isotretinoin. The second pregnancy test must be done in a lab during the first 5 days of my menstrual period right before starting isotretinoin therapy treatment, or as instructed by my doctor. I will then have 1 pregnancy test; in a lab:
   - every month during treatment
   - at the end of treatment
   - and 1 month after stopping treatment

   I must not start taking isotretinoin until I am sure that I am not pregnant, have negative results from 2 pregnancy tests, and the second test has been done in a lab.
   Initial: _____
10. I have read and understand the materials my doctor has provided to me, including *The iPLEDGE Program Guide for Isotretinoin for Female Patients Who Can Get Pregnant, The iPLEDGE Birth Control Workbook* and *The iPLEDGE Program Patient Introductory Brochure.*

    My doctor provided me and asked me to watch a video about birth control and a video about birth defects and isotretinoin.

    I was told about a private counseling line that I may call for more information about birth control. I have received information on emergency birth control.
    Initial: _____
11. I must stop taking isotretinoin right away and call my doctor if I get pregnant, miss my expected menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods at any time.
    Initial: _____
12. My doctor provided me information about the purpose and importance of providing information to the iPLEDGE Program should I become pregnant while taking isotretinoin or within one month of the last dose. I understand that if I become pregnant, information about my pregnancy, my health, and my baby's health may be shared with the makers of isotretinoin, authorized parties who maintain the iPLEDGE Program for the makers of isotretinoin, and government health regulatory authorities.
    Initial: _____
13. I understand that being qualified to receive isotretinoin in the iPLEDGE Program means that I:
    - have had 2 negative urine or blood pregnancy tests before receiving the first isotretinoin prescription. The second test must be done in a lab. I must have a negative result from a urine or blood pregnancy test done in a lab repeated each month before I receive another isotretinoin prescription.
    - have chosen and agreed to use 2 forms of effective birth control at the same time. At least 1 method must be a primary form of birth control, **unless I have chosen never to have sexual contact with a male (abstinence)**, or I have undergone a hysterectomy. I must use 2 forms of birth control for at least 1 month before I start isotretinoin therapy, during therapy, and for 1 month after stopping therapy. I must receive counseling, repeated on a monthly basis, about birth control and behaviors associated with an increased risk of pregnancy.
    - have signed a Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) that contains warnings about the chance of possible birth defects if I am pregnant or become pregnant and my unborn baby is exposed to isotretinoin.
    - have interacted with the iPLEDGE Program before starting isotretinoin and on a monthly basis to answer questions on the program requirements and to enter my two chosen forms of birth control.
    Initial: _____

My doctor has answered all my questions about isotretinoin and I understand that it is my responsibility not to get pregnant 1 month before, during isotretinoin treatment, or for 1 month after I stop taking isotretinoin.

Initial: _____

I now authorize my doctor _____ to begin my treatment with isotretinoin.

Patient Signature: _____ Date: _____

Parent/Guardian Signature (if under age 18): _____ Date: _____

Please print: Patient Name and Address_____ Telephone_____

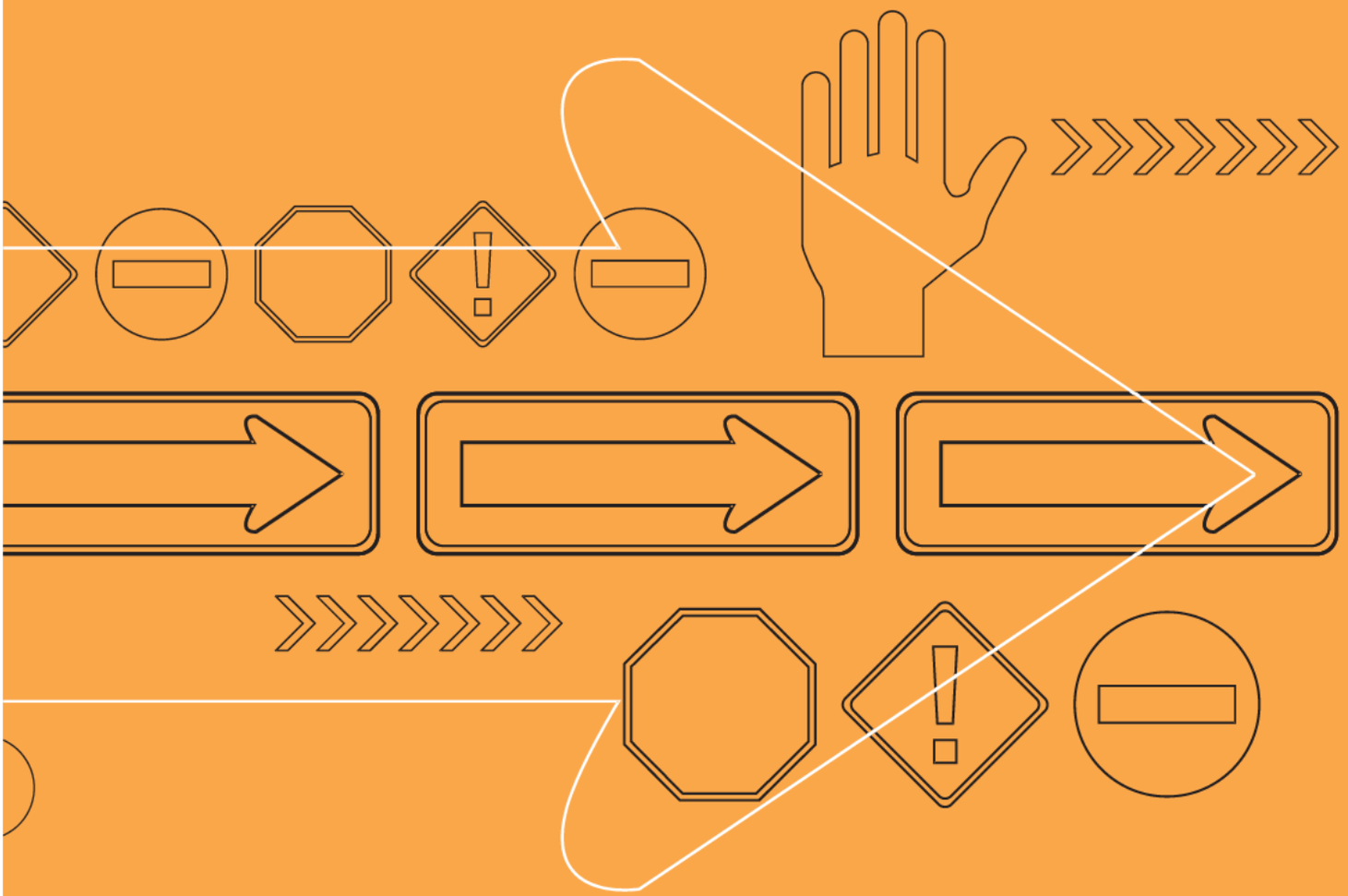
I have fully explained to the patient, _____, the nature and purpose of the treatment described above and the risks to females of reproductive potential. I have asked the patient if she has any questions regarding her treatment with isotretinoin and have answered those questions to the best of my ability.

Doctor Signature: _____ Date: _____

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

Reference ID: 3956479

Patient Flowchart



A flowchart to assist you with the iPLEDGE Program requirements

Reference ID: 3956479

REGISTERED PATIENTS

iPLEDGE™
Committed to Pregnancy Prevention

Females of reproductive potential (FRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Sign** a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- **Get** a screening urine/blood pregnancy test
- **Receive** patient ID card
- **Choose** 2 effective forms of birth control
- **Start** using the 2 forms of birth control simultaneously for at least 1 month
- **Get** a second pregnancy test within the first 5 days of your menstrual period (patient with irregular cycle please check with your prescriber) in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and to enter the 2 chosen forms of birth control. You can only answer your questions after your doctor has entered your test results into the iPLEDGE Program System
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **Use** the 2 forms of birth control Simultaneously
- **See** your doctor for a monthly pregnancy test in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and confirm the 2 forms of birth control
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Get** a pregnancy test in an approved lab the last dose
- **Continue** to use the 2 forms of birth control simultaneously for 1 month after the last dose
- **Do not** donate blood for 1 month after the last dose
- **Get** a final pregnancy test 1 month after the last dose

Male patients/Females of non-reproductive potential (FNRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Receive** patient ID card
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **See** your doctor to get a prescription
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Do not** donate blood for 1 month after after your last dose

*You can access the system via the web site, **www ipledgeprogram.com**, or the telephone, **1-866-495-0654**.

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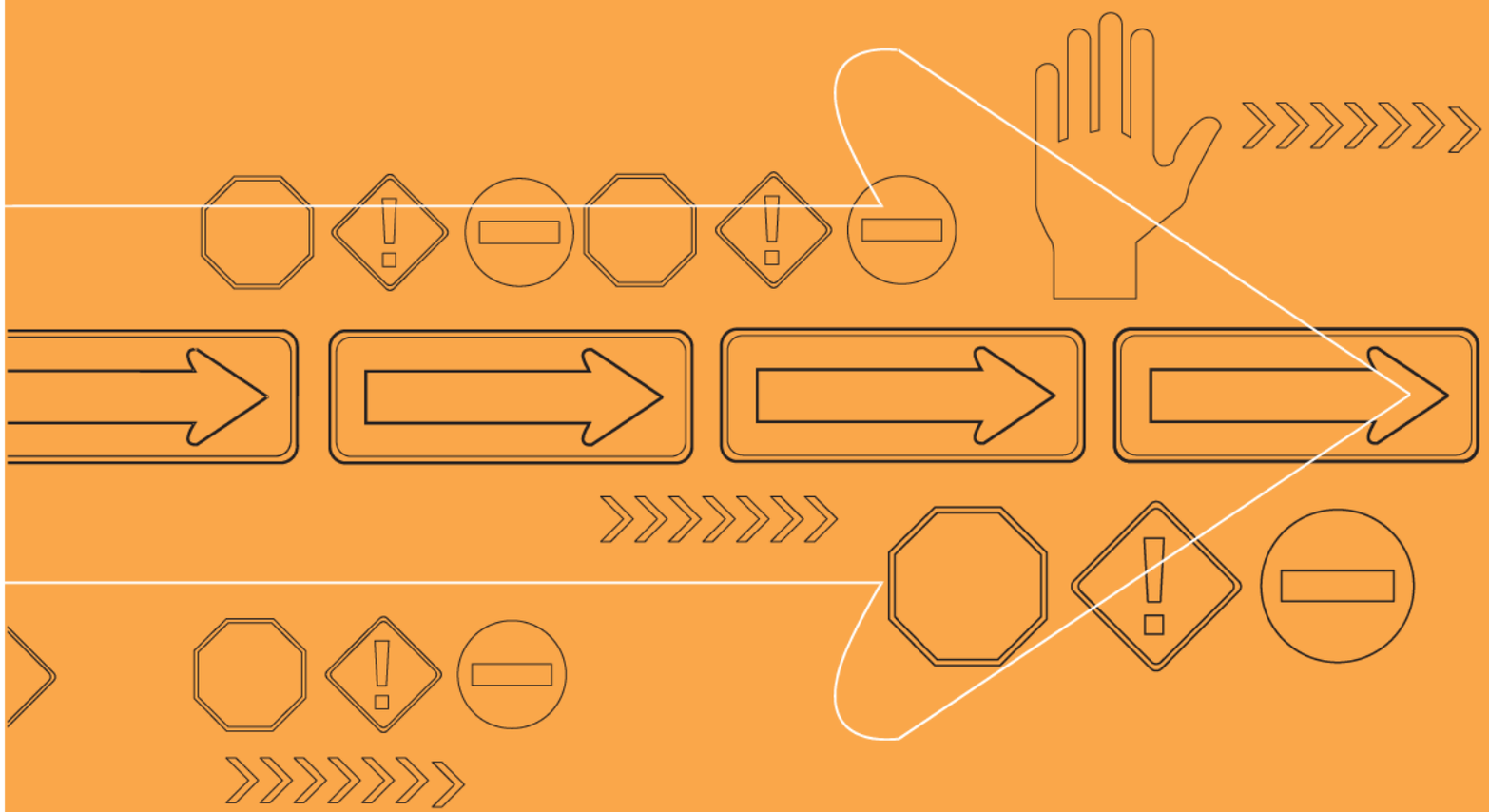

www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Most Recent Modification: July 2016

The iPLEDGE Program

Isotretinoin Educational Kit For Male Patients And Female Patients Who Cannot Get Pregnant

The tools you need to help you prepare and plan treatments during the course of isotretinoin treatment

CONTENTS

- Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant
- Patient Information/Informed Consent (for all patients)
- Patient Identification Card
- Patient Flowchart

W N G

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

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IMPO TA T OTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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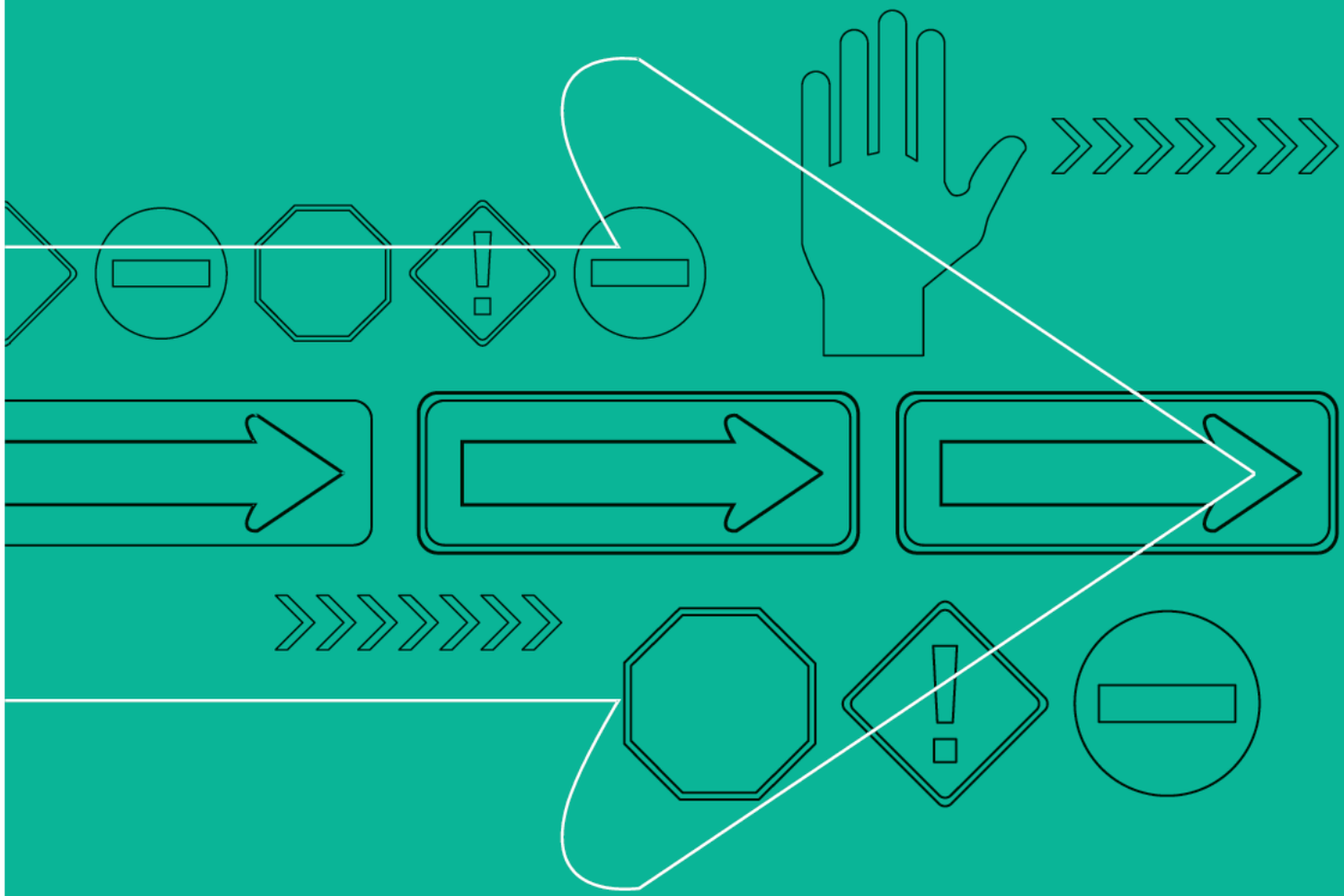
Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant



The guide to help you prepare and plan treatments during the course of isotretinoin treatment

Reference ID: 3956479

Most Recent Modification: July 2016

The iPLEDGE Program

Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant

The resource to help you prepare and plan treatments during the course of isotretinoin treatment

W

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Committed to Pregnancy Prevention

Reference ID: 3956479

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant

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ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.

Even if you are a male or a female patient who cannot get pregnant, the iPLEDGE Program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin. You should also learn about the side effects and the precautions and warnings.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant* and make sure you understand the requirements of the iPLEDGE Program. Then decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR MALE PATIENTS AND FEMALE PATIENTS WHO CANNOT GET PREGNANT

Birth Defects

There is a very high chance that babies born to female patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a female patient takes isotretinoin for only a short time. It may also happen if a pregnant female receives a blood transfusion from someone taking isotretinoin.

Do male patients taking isotretinoin need to worry about birth defects?

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.

If you are worried about isotretinoin birth defects from sperm, you can use a male latex condom to help prevent pregnancy. Use a condom each and every time you have intercourse (sex) while you are taking isotretinoin and for 1 month after you stop taking it.

Can isotretinoin affect a male patient's ability to father healthy children?

Studies on isotretinoin did not show effects on sperm count, how sperm look, or how well they swim and move.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant female gets blood from you. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 8 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant and your educational kit are resources for the information you need about isotretinoin and the iPLEDGE Program. The iPLEDGE Program also has a web site and an automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE Program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID card, and other program materials. You use these to log in to the system. (*see page 5*)

After you have been registered in the iPLEDGE Program by your doctor, you will receive your iPLEDGE Program password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE Program system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant explains the information about the iPLEDGE Program before, during, and after your isotretinoin treatment. Here is a general overview:

- Learn about the iPLEDGE Program and the isotretinoin side effects and risks in pregnancy.
- Plan for treatment and appointments.
- Sign the Patient Information/Informed Consent (for all patients) form.
- Keep monthly appointments.
- Do not donate blood during your treatment or 1 month after your last dose.
- Do not share isotretinoin.

You can use the checklist on the next page as a quick reminder of the program information during your isotretinoin treatment.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient.

Male patients and female patients who cannot get pregnant

The prescription window is 30 days and starts on the date the prescriber enters as the date of your office visit. This date is counted as DAY 1.

To determine the end date of your 30-day prescription window, you should add 29 days to the date of your office visit.

After 11:59 p.m. Eastern Time on the last day of the 30-day prescription window, you can no longer obtain your prescription, and must start the process over to get a new 30-day prescription window.

Before Treatment

PLANNING

- ❑ **Plan** your course of treatment (about 4 to 5 months).
- ❑ **Talk** with your doctor about isotretinoin and the iPLEDGE Program.
- ❑ **Sign** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Get** your patient ID card containing your patient ID number from your doctor. (*see page 5*)
- ❑ **Receive** your password in the mail.

PRESCRIPTION

- ❑ **Get** your prescription for a maximum of up to a 30-day supply.
- ❑ **Obtain** your prescription within the 30-day prescription window counting your office visit as DAY 1. the (*see page 6*)

During Treatment

- ❑ Keep your appointments every month to get your prescription.
- ❑ **Obtain** your prescription within the 30-day prescription window counting the office visit as DAY 1. If you do not obtain your prescription within the 30-day prescription window, you will be required to start the process over again by visiting your doctor.
- ❑ **Do not donate blood.**

After Treatment

- ❑ **Do not donate** blood for 1 month after your last dose.

Reference ID: 3956479

THE iPLEDGE PROGRAM CHECKLIST INFORMATION

Plan Your Course Of Treatment

The most isotretinoin you can get at any one time is a maximum of up to a 30-day supply. You will need to see your doctor each month to get a new prescription.

Get Your Patient ID Number And ID Cards

Your doctor will give you your patient ID cards, containing your patient ID number, when you start the iPLEDGE Program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. Write your number down as soon as you receive it, and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled and dispensed at the pharmacy
- When you log in to the iPLEDGE Program system, either the web site, **www.ipledgeprogram.com,** or phone line, **1-866-495-0654**

About The iPLEDGE Program Automated System

The first time you login to the iPLEDGE Program (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using the iPLEDGE Program system.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can obtain your prescription
- Change to a new doctor
- Get information about isotretinoin
- View information about your current status
- View FAQ's (Frequently Asked Questions)

If you lose your Patient Identification Cards, and cannot remember your patient ID number, contact your doctor.

Reference ID: 3956479

Informed Consents

You must sign the Patient Information/Informed Consent (for all patients) form to be in the iPLEDGE Program.

Signing the informed consent means you understand that there are risks associated with taking isotretinoin.

Obtain Your Prescription

Obtain your isotretinoin prescriptions only at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com,** has a list of registered pharmacies. Log in and choose "Find a Participating Pharmacy" in the left navigation.

Your pharmacist will contact the iPLEDGE Program system before filling your prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only obtain isotretinoin if:

- Your doctor entered your patient information in the iPLEDGE system
- You can obtain the prescription within the 30-day prescription window, counting the office visit as DAY 1. Please see your doctor if you did not obtain your prescription within the 30-day prescription window.

The system will automatically compute the "Do Not Dispense To Patient After" date for your pharmacist.

To figure out the last date you can obtain your prescription, add 29 days to the date of your office visit. For example:

Day 1 and Day of the office visit	Day 2 – Day 29	Day 30 – Last day to obtain prescription
(Friday, March 1)	(Saturday, March 2 thru Friday, March 29)	(Saturday, March 30)

The 30-day prescription window expires at 11:59 p.m. Eastern Time on Day 30 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 30-day prescription window expires before you obtain your prescription, you can start a new 30-day prescription window right away, but you must repeat the program requirements to get another prescription.

Additional information about your status, can be found by selecting "My Program Status" on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.

Reference ID: 3956479

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

After Your Last Dose

It is very important that:

- You do NOT give blood for 1 month after your last dose
- You do not share any leftover isotretinoin with anyone

Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE Program system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE web site, **www.ipledgeprogram.com,** or phone line, **1-866-495-0654.**
You need your patient ID number and password to log in to the system.

To change your doctor on the iPLEDGE Program web site:

1. Log in
2. Choose "Change Primary Prescriber" from the menu
3. You need to enter the following information about your new doctor:
   - First and last name
   - City
   - Phone number

To change your doctor on the automated phone line:

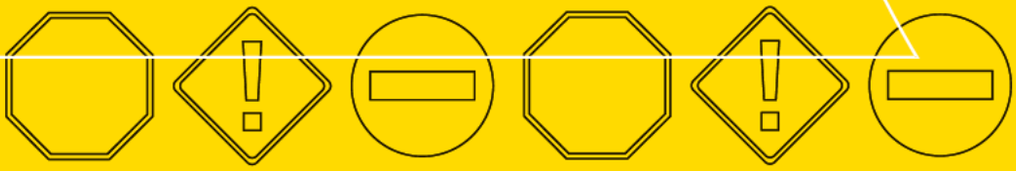
1. Log in
2. Select the option for "More Choices"
3. Select "Change Your Prescriber"
4. Follow the prompts to enter the new information

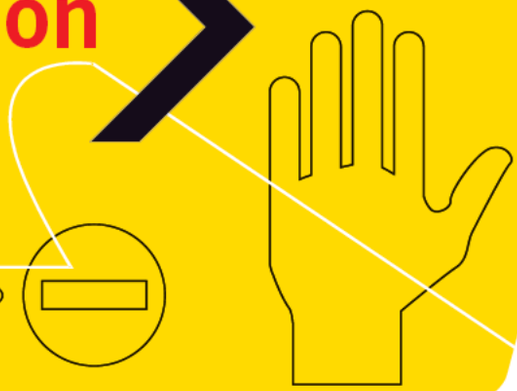
The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE Program system before being able to give you a prescription.

Reference ID: 3956479

Safety Information

ABOUT ISOTRETINOIN





WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
   Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
     Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Reference ID: 3956479

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

Reference ID: 3956479

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do **not** take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. **You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE Program system, go to **www.ipledgeprogram.com** or call **1-866-495-0654.**

Reference ID: 3956479

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

Reference ID: 3956479

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Reference ID: 3956479

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children.**

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com.**

Reference ID: 3956479

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For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, ask your doctor, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call **1-866-495-0654**.

For private birth control information, you can reach the iPLEDGE Program automated phone line 24 hours a day, 7 days a week at **1-866-495-0654**. You can learn about different subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479

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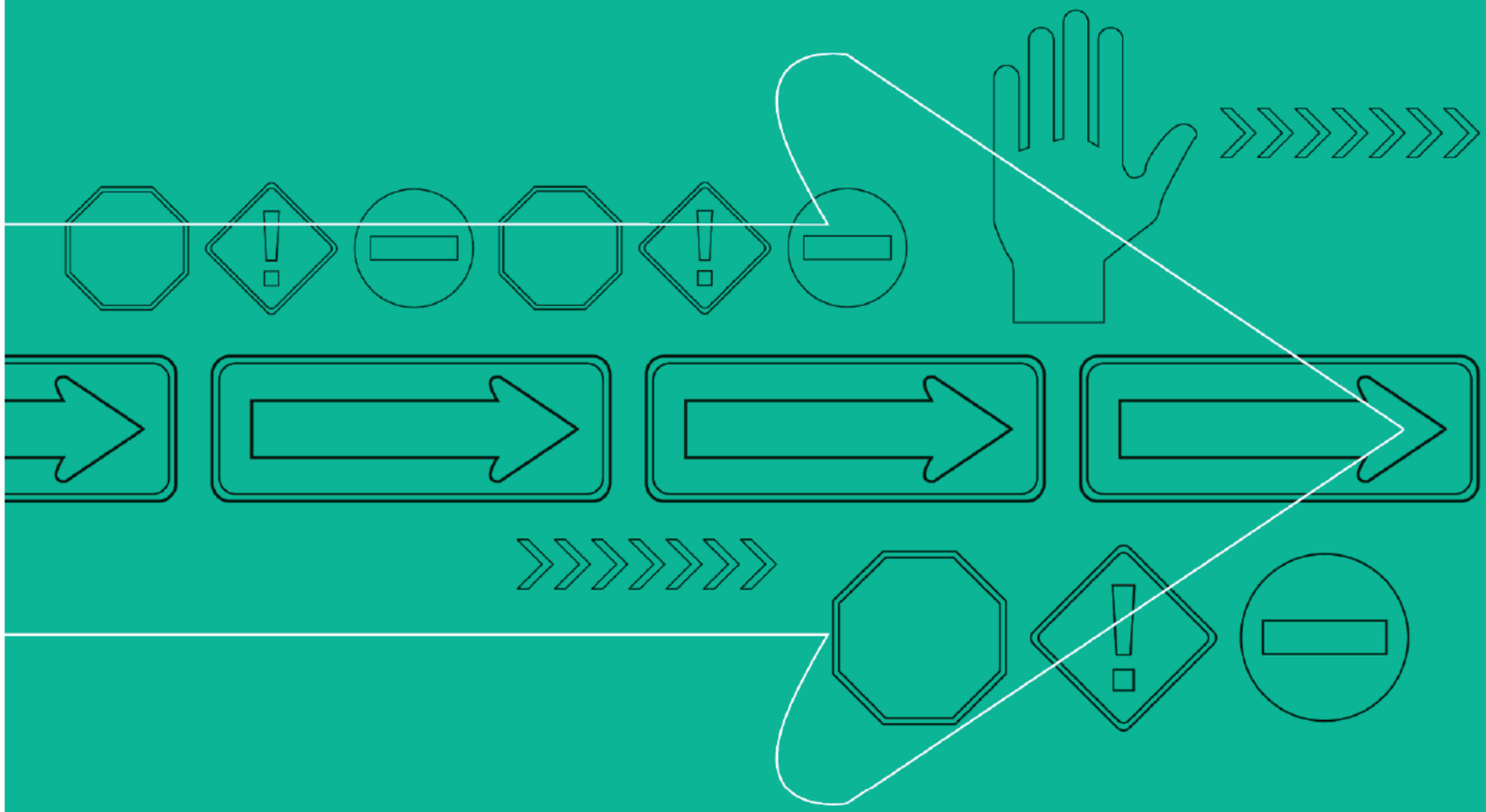

www.ipledgeprogram.com 1-866-495-0654

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For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

P T

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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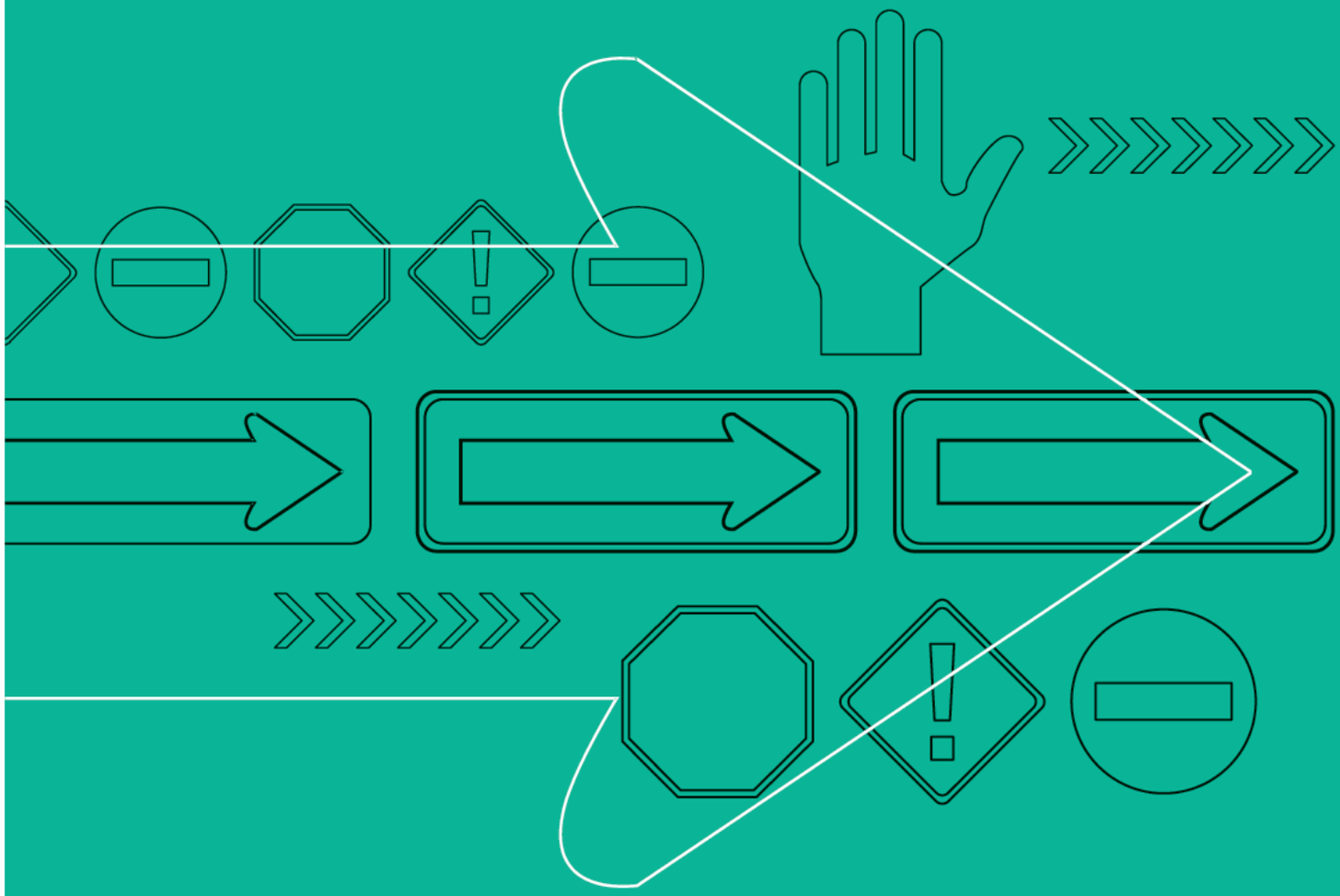
Patient Information/Informed Consent



Important form you must sign before you begin taking isotretinoin

iPLEDGE™
Committed to Pregnancy Prevention

iPLEDGE–Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

Patient Information/Informed Consent (for all patients):

To be completed by patient (and parent or guardian if patient is under age 18) and signed by the doctor.

Read each item below and initial in the space provided if you understand each item and agree to follow your doctor's instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not take isotretinoin if there is anything that you do not understand about all the information you have received about using isotretinoin.

1. I, _____
(Patient's Name)

   understand that isotretinoin is a medicine used to treat severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, severe nodular acne can lead to permanent scars.

   Initials: _____

2. My doctor has told me about my choices for treating my acne.

   Initials: _____

3. I understand that there are serious side effects that may happen while I am taking isotretinoin. These have been explained to me. These side effects include serious birth defects in babies of pregnant patients. [Note: There is a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)].

   Initials: _____

4. I understand that some patients, while taking isotretinoin or soon after stopping isotretinoin, have become depressed or developed other serious mental problems. Symptoms of depression include sad, "anxious" or empty mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent. No one knows if isotretinoin caused these behaviors or if they would have happened even if the person did not take isotretinoin. Some people have had other signs of depression while taking isotretinoin (see #7).

   Initials: _____

5. Before I start taking isotretinoin, I agree to tell my doctor if I have **ever** had symptoms of depression (see #7), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems. Being psychotic means having a loss of contact with reality, such as hearing voices or seeing things that are not there.

   Initials: _____

6. Before I start taking isotretinoin, I agree to tell my doctor if, to the best of my knowledge, anyone in my family has ever had symptoms of depression, been psychotic, attempted suicide, or had any other serious mental problems.

   Initials: _____

7. Once I start taking isotretinoin, I agree to stop using isotretinoin and tell my doctor right away if any of the following signs and symptoms of depression or psychosis happen. I:
   - Start to feel sad or have crying spells
   - Lose interest in activities I once enjoyed
   - Sleep too much or have trouble sleeping
   - Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
   - Have a change in my appetite or body weight
   - Have trouble concentrating
   - Withdraw from my friends or family
   - Feel like I have no energy
   - Have feelings of worthlessness or guilt
   - Start having thoughts about hurting myself or taking my own life (suicidal thoughts)
   - Start acting on dangerous impulses
   - Start seeing or hearing things that are not real

   Initials: _____

8. **I agree to return to see my doctor every month I take isotretinoin to get a new prescription for isotretinoin, to check my progress, and to check for signs of side effects.**

   Initials: _____

9. Isotretinoin will be prescribed just for me — I will not share isotretinoin with other people because it may cause serious side effects, including birth defects.

   Initials: _____

10. I will not give blood while taking isotretinoin or for 1 month after I stop taking isotretinoin. I understand that if someone who is pregnant gets my donated blood, her baby may be exposed to isotretinoin and may be born with serious birth defects.

    Initials: _____

11. I have read *The iPLEDGE Program Patient Introductory Brochure* and other materials my provider provided me containing important safety information about isotretinoin. I understand all the information I received.

    Initials: _____

12. My doctor and I have decided I should take isotretinoin. I understand that I must be qualified in the iPLEDGE Program to have my prescription filled each month. I understand that I can stop taking isotretinoin at any time. I agree to tell my doctor if I stop taking isotretinoin.

    Initials: _____

I now allow my doctor _____ to begin my treatment with isotretinoin.

Patient Signature: _____ Date: _____

Parent/Guardian Signature (if under age 18): _____ Date: _____

Patient Name (print) _____

Patient Address _____ Telephone_____–_____–_____

I have:

- fully explained to the patient, _____, the nature and purpose of isotretinoin treatment, including its benefits and risks
- provided the patient the appropriate educational materials, *The iPLEDGE Program Patient Introductory Brochure* and asked the patient if he/she has any questions regarding his/her treatment with isotretinoin
- answered those questions to the best of my ability

Doctor Signature: _____Date: _____

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

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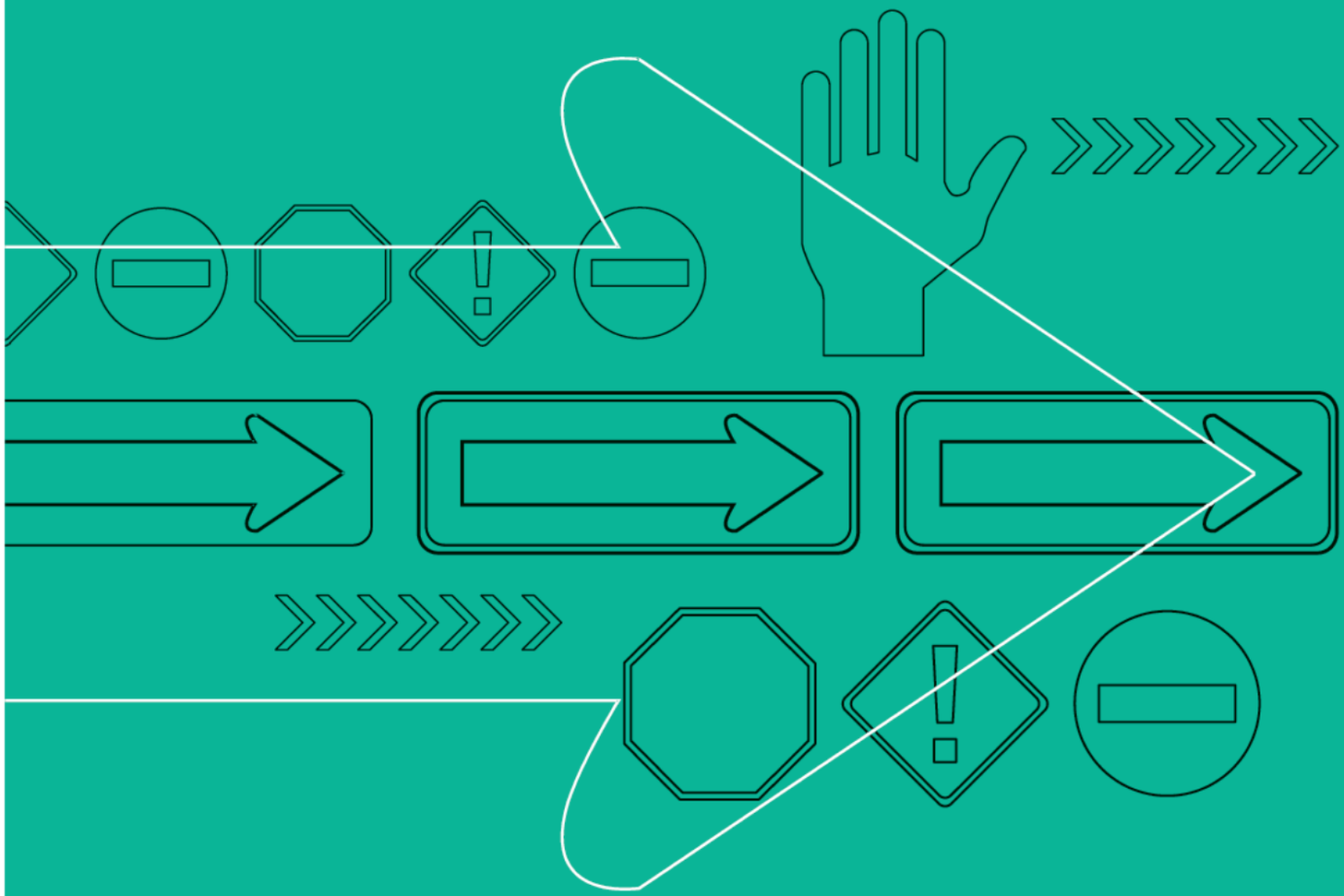
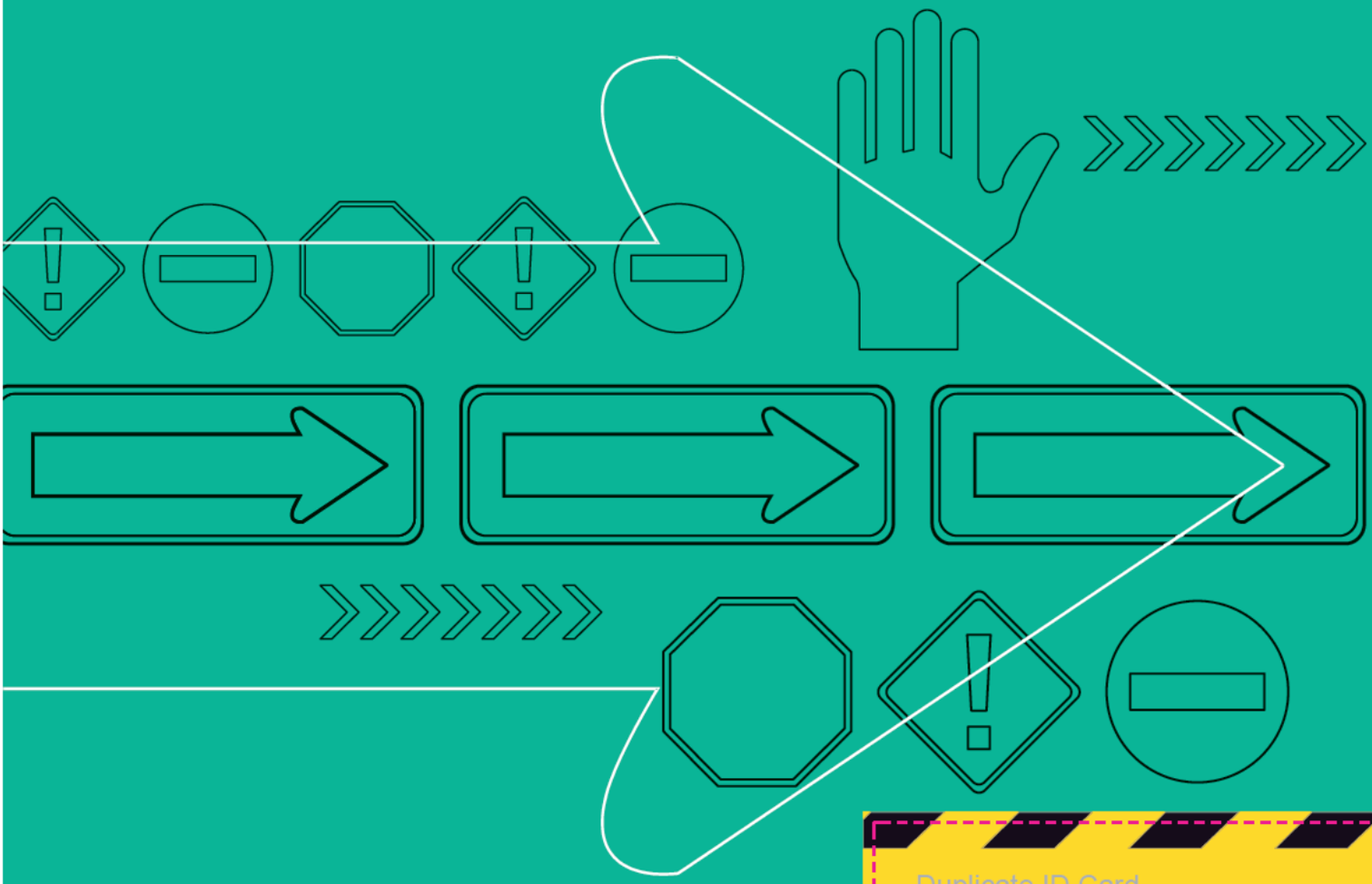
PRE_FORM01

Reference ID: 3956479

Patient Identification Card



- The card you need to bring with you to doctor visits and to the pharmacy while on isotretinoin



Peel off sticker for patient's file

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescr pition to the pharmacy within your prescription window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Pre

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your prescription window
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- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

- Visit your doctor monthly
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- Take this card and your prescription to the pharmacy within your prescription window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you are pregnant. Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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Stop isotretinoin and call your doctor right away if you are pregnant. Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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Stop isotretinoin and call your doctor right away if you are pregnant. Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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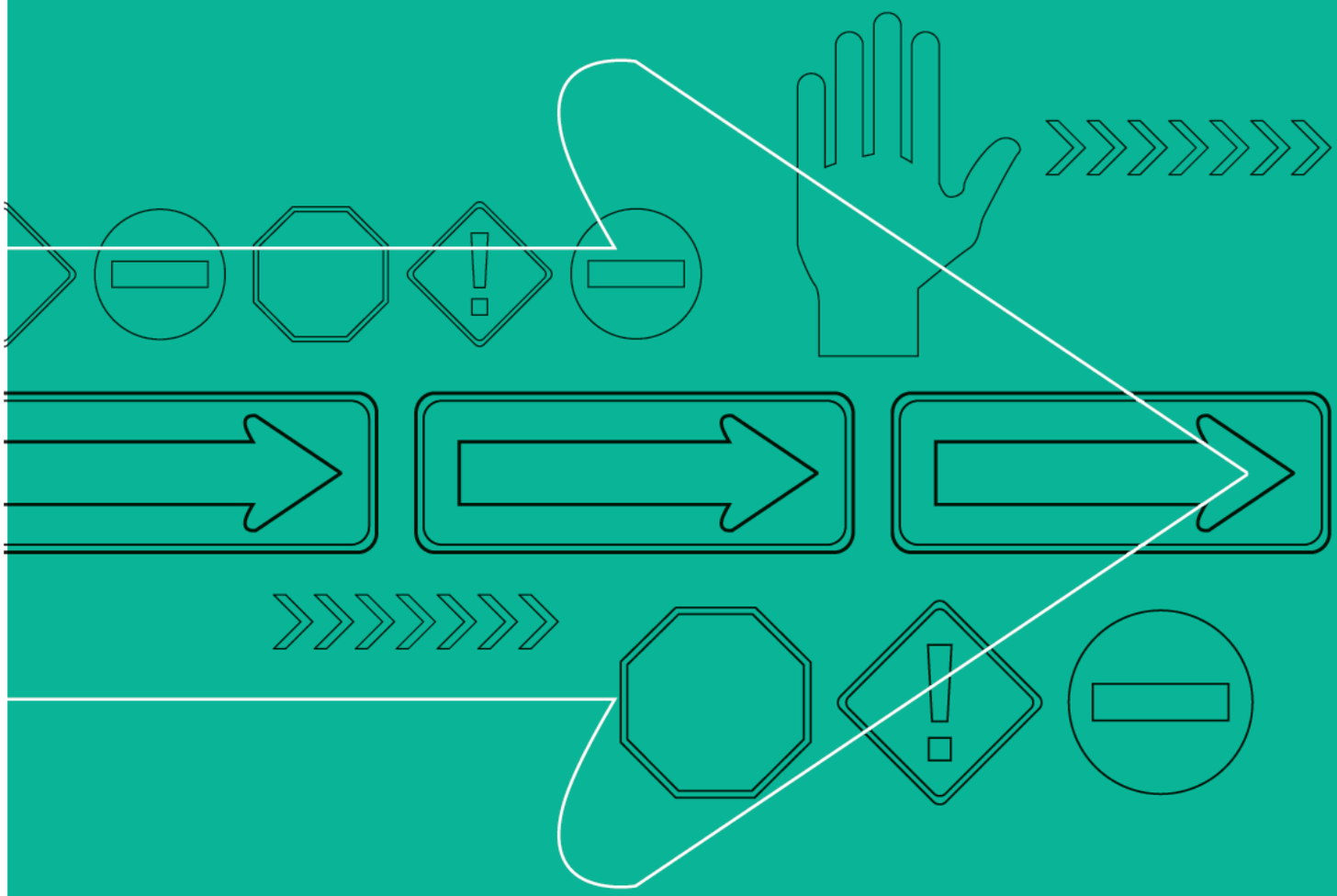

A flowchart to assist you with the iPLEDGE Program requirements

REGISTERED PATIENTS

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Females of reproductive potential (FRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Sign** a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- **Get** a screening urine/blood pregnancy test
- **Receive** patient ID card
- **Choose** 2 effective forms of birth control
- **Start** using the 2 forms of birth control simultaneously for at least 1 month
- **Get** a second pregnancy test within the first 5 days of your menstrual period (patient with irregular cycle please check with your prescriber) in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and to enter the 2 chosen forms of birth control. You can only answer your questions after your doctor has entered your test results into the iPLEDGE Program System
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **Use** the 2 forms of birth control simultaneously
- **See** your doctor for a monthly pregnancy test in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and confirm the 2 forms of birth control
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Get** a pregnancy test in an approved lab after the last dose
- **Continue** to use the 2 forms of birth control simultaneously for 1 month after the last dose
- **Do not** donate blood for 1 month after the last dose
- **Get** a final pregnancy test 1 month after the last dose

Male patients/Females of non-reproductive potential (FNRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Receive** patient ID card
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **See** your doctor to get a prescription
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Do not** donate blood for 1 month after your last dose

*You can access the system via the web site, **www ipledgeprogram.com**, or the telephone, **1-866-495-0654**.

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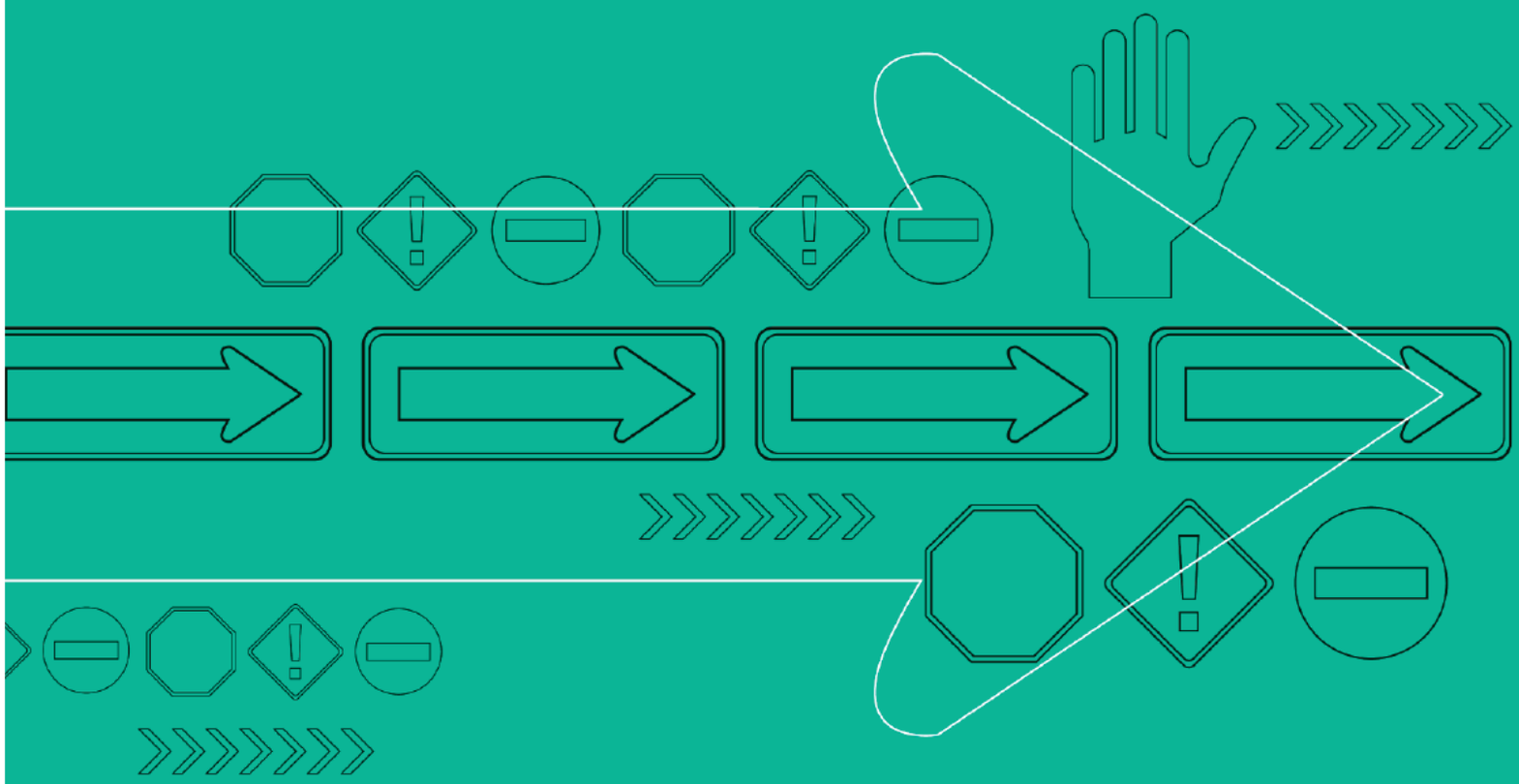
Reference ID: 3956479



www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions only from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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Most Recent Modification: July 2016

The iPLEDGE Program

Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant

The resource to help you prepare and plan treatments during the course of isotretinoin treatment

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

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The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant

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Reference ID: 3956479

ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.

Even if you are a male or a female patient who cannot get pregnant, the iPLEDGE Program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin. You should also learn about the side effects and the precautions and warnings.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant* and make sure you understand the requirements of the iPLEDGE Program. Then decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR MALE PATIENTS AND FEMALE PATIENTS WHO CANNOT GET PREGNANT

Birth Defects

There is a very high chance that babies born to female patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a female patient takes isotretinoin for only a short time. It may also happen if a pregnant female receives a blood transfusion from someone taking isotretinoin.

Do male patients taking isotretinoin need to worry about birth defects?

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. Approximately 3 to 5 babies in 100 (3% to 5%) are born with some kind of birth defect from other causes, not from isotretinoin.

If you are worried about isotretinoin birth defects from sperm, you can use a male latex condom to help prevent pregnancy. Use a condom each and every time you have intercourse (sex) while you are taking isotretinoin and for 1 month after you stop taking it.

Can isotretinoin affect a male patient's ability to father healthy children?

Studies on isotretinoin did not show effects on sperm count, how sperm look, or how well they swim and move.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant female gets blood from you. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 8 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant and your educational kit are resources for the information you need about isotretinoin and the iPLEDGE Program. The iPLEDGE Program also has a web site and an automated phone system.

- Web site: **www.ipledgeprogram.com**
- Phone system: **1-866-495-0654**

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE Program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID card, and other program materials. You use these to log in to the system. (*see page 5*)

After you have been registered in the iPLEDGE Program by your doctor, you will receive your iPLEDGE Program password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE Program system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Male Patients And Female Patients Who Cannot Get Pregnant explains the information about the iPLEDGE Program before, during, and after your isotretinoin treatment. Here is a general overview:

- Learn about the iPLEDGE Program and the isotretinoin side effects and risks in pregnancy.
- Plan for treatment and appointments.
- Sign the Patient Information/Informed Consent (for all patients) form.
- Keep monthly appointments.
- Do not donate blood during your treatment or 1 month after your last dose.
- Do not share isotretinoin.

You can use the checklist on the next page as a quick reminder of the program information during your isotretinoin treatment.

THE iPLEDGE PROGRAM CHECKLIST

All patients have a specific period of time in which they can obtain their prescription. This is called the "prescription window" and its start and end dates depend on the type of patient.

Male patients and female patients who cannot get pregnant

The prescription window is 30 days and starts on the date the prescriber enters as the date of your office visit. This date is counted as DAY 1.

To determine the end date of your 30-day prescription window, you should add 29 days to the date of your office visit.

After 11:59 p.m. Eastern Time on the last day of the 30-day prescription window, you can no longer obtain your prescription, and must start the process over to get a new 30-day prescription window.

Before Treatment

PLANNING

- ❑ **Plan** your course of treatment (about 4 to 5 months).
- ❑ **Talk** with your doctor about isotretinoin and the iPLEDGE Program. ❑
- **Sign** the Patient Information/Informed Consent (for all patients) form. ❑
- **Get** your patient ID card containing your patient ID number from your doctor. (*see page 5*)
- ❑ **Receive** your password in the mail.

PRESCRIPTION

- ❑ **Get** your prescription for a maximum of up to a 30-day supply.
- ❑ **Obtain** your prescription within the 30-day prescription window counting your office visit as DAY 1. the (*see page 6*)

During Treatment

- ❑ Keep your appointments every month to get your prescription.
- ❑ **Obtain** your prescription within the 30-day prescription window counting the office visit as DAY 1. If you do not obtain your prescription within the 30-day prescription window, you will be required to start the process over again by visiting your doctor.
- ❑ **Do not donate blood.**

After Treatment

- ❑ **Do not donate** blood for 1 month after your last dose.

THE iPLEDGE PROGRAM CHECKLIST INFORMATION

Plan Your Course Of Treatment

The most isotretinoin you can get at any one time is a maximum of up to a 30-day supply. You will need to see your doctor each month to get a new prescription.

Get Your Patient ID Number And ID Cards

Your doctor will give you your patient ID cards, containing your patient ID number, when you start the iPLEDGE Program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. Write your number down as soon as you receive it, and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled and dispensed at the pharmacy
- When you log in to the iPLEDGE Program system, either the web site, **www.ipledgeprogram.com,** or phone line, **1-866-495-0654**

About The iPLEDGE Program Automated System

The first time you login to the iPLEDGE Program (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using the iPLEDGE Program system.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can obtain your prescription
- Change to a new doctor
- Get information about isotretinoin
- View information about your current status
- View FAQ's (Frequently Asked Questions)

If you lose your Patient Identification Cards, and cannot remember your patient ID number, contact your doctor.

Informed Consents

You must sign the Patient Information/Informed Consent (for all patients) form to be in the iPLEDGE Program.

Signing the informed consent means you understand that there are risks associated with taking isotretinoin.

Obtain Your Prescription

Obtain your isotretinoin prescriptions only at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

The web site, **www.ipledgeprogram.com,** has a list of registered pharmacies. Log in and choose "Find a Participating Pharmacy" in the left navigation.

Your pharmacist will contact the iPLEDGE Program system before filling your prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only obtain isotretinoin if:

- Your doctor entered your patient information in the iPLEDGE system
- You can obtain the prescription within the 30-day prescription window, counting the office visit as DAY 1. Please see your doctor if you did not obtain your prescription within the 30-day prescription window.

The system will automatically compute the "Do Not Dispense To Patient After" date for your pharmacist.

To figure out the last date you can obtain your prescription, add 29 days to the date of your office visit. For example:

Day 1 and Day of the office visit	Day 2 – Day 29	Day 30 – Last day to obtain prescription
(Friday, March 1)	(Saturday, March 2 thru Friday, March 29)	(Saturday, March 30)

The 30-day prescription window expires at 11:59 p.m. Eastern Time on Day 30 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 30-day prescription window expires before you obtain your prescription, you can start a new 30-day prescription window right away, but you must repeat the program requirements to get another prescription.

Additional information about your status, can be found by selecting "My Program Status" on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.

Reference ID: 3956479

A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via www.ipledgeprogram.com.

After Your Last Dose

It is very important that:

- You do NOT give blood for 1 month after your last dose
- You do not share any leftover isotretinoin with anyone

Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE Program system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE web site, **www.ipledgeprogram.com,** or phone line, **1-866-495-0654.**
You need your patient ID number and password to log in to the system.

To change your doctor on the iPLEDGE Program web site:

1. Log in
2. Choose "Change Primary Prescriber" from the menu
3. You need to enter the following information about your new doctor:
   - First and last name
   - City
   - Phone number

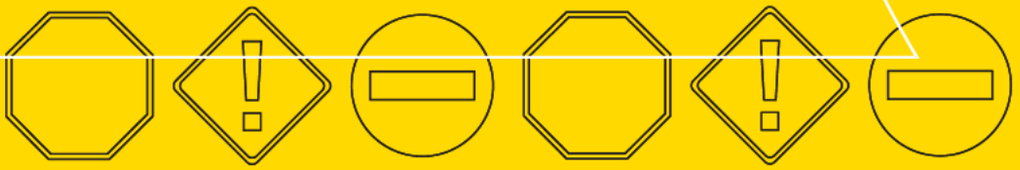
To change your doctor on the automated phone line:

1. Log in
2. Select the option for "More Choices"
3. Select "Change Your Prescriber"
4. Follow the prompts to enter the new information

The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE Program system before being able to give you a prescription.

Safety Information

ABOUT ISOTRETINOIN



WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
   Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
     Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Reference ID: 3956479

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

Reference ID: 3956479

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do **not** take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. **You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE Program system, go to **www.ipledgeprogram.com** or call **1-866-495-0654.**

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

Reference ID: 3956479

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?")**
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

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Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Reference ID: 3956479

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children.**

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com.**

Reference ID: 3956479

NOTES:

NOTES:

For More Information About Isotretinoin And The iPLEDGE Program

If you have questions about the iPLEDGE Program, ask your doctor, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call **1-866-495-0654**.

For private birth control information, you can reach the iPLEDGE Program automated phone line 24 hours a day, 7 days a week at **1-866-495-0654**. You can learn about different subjects, including:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

Isotretinoin Products

To get information about specific brands of isotretinoin, the contact information for individual makers can be obtained by calling 1-866-495-0654 or via www.ipledgeprogram.com.

Reference ID: 3956479

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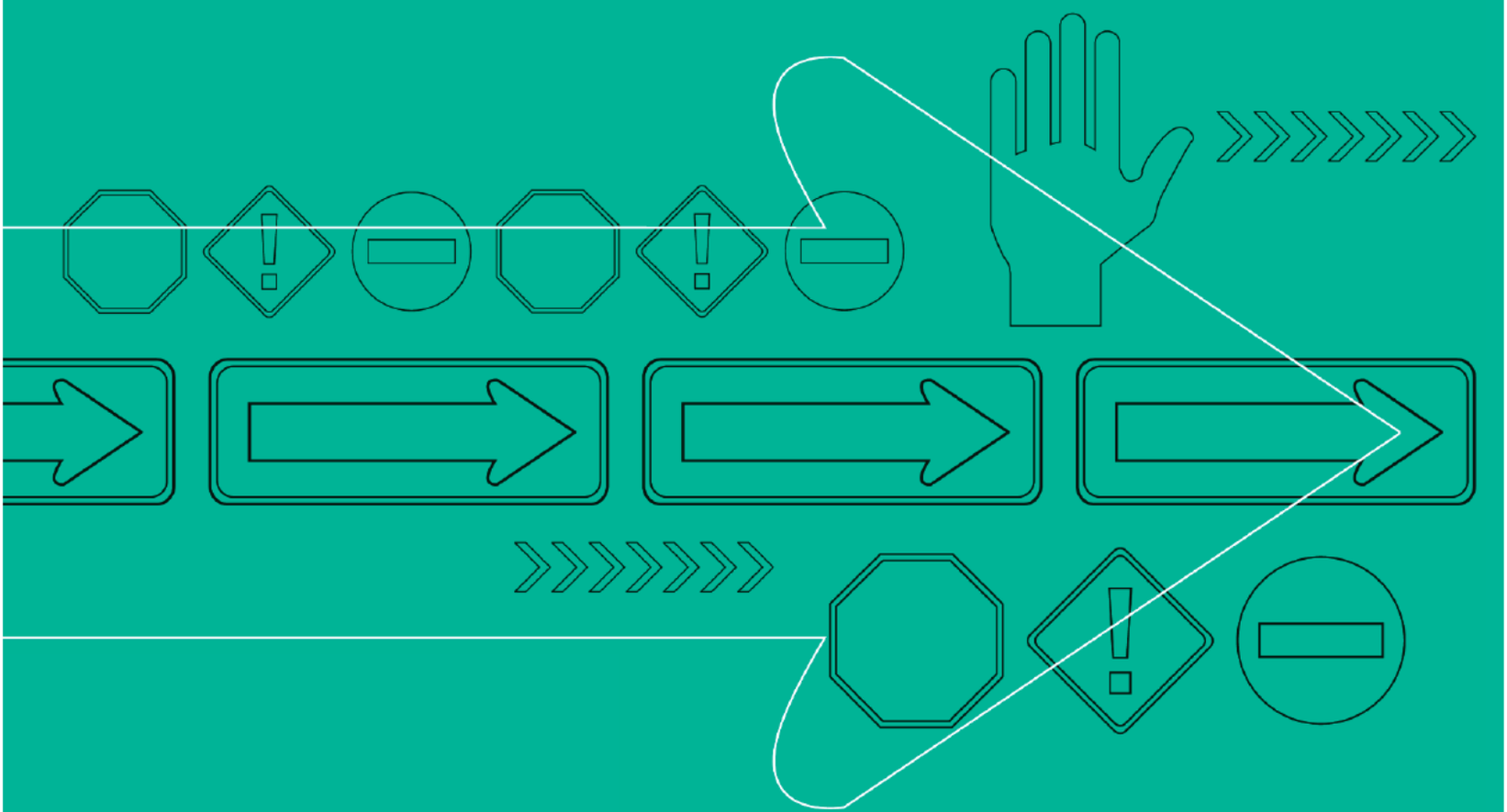

www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.

iPLEDGE™
Committed to Pregnancy Prevention

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Reference ID: 3956479

II.D.2 Patient Understanding

Patient Comprehension Questions

Program Steps	
One goal of the iPLEDGE Program is making sure pregnant women do not take isotretinoin	1. True
	2. False
You are in your third month of treatment, in order to get your isotretinoin prescription, you must	1. Have a urine test for infection.
	2. Have a negative pregnancy test done in a laboratory, discuss birth control with your doctor and answer questions in the iPLEDGE Program system.
The confidential iPLEDGE Program Pregnancy Registry collects information on pregnancies that happen during isotretinoin treatment or within 1 month after the last dose	1. True
	2. False
Each month you need to answer questions and:	1. Enter 2 forms of birth control you are using.
	2. Do a home pregnancy test to show the pharmacist.
For 1 month after your last dose, you must use 2 effective forms of birth control together all the time	1. True
	2. False
Your doctor tells you that you to come back 1 month after your final dose. You return to the office to:	1. Get a prescription for 30 days.
	2. Talk with your doctor about birth control.
	3. Get the last pregnancy test.
Your doctor tells you that you need to have a pregnancy test each month. You would:	1. Refuse the test because you know you are not pregnant.
	2. Agree to have the pregnancy test because it is important to know if you are pregnant before taking isotretinoin.
	3. Wait a week before getting the test done.
You must keep your appointment every month because:	1. It is important for you and your doctor to interact before you get a maximum 30 day supply of isotretinoin each month.
	2. You need to sign a consent form each month.
	You need to tell your doctor where to call in your prescription.

Reference ID: 3956479

General Contraception Requirements	
Many women who became pregnant while taking isotretinoin were using only 1 form of birth control.	1. True 2. False
Using alcohol and drugs can make it more difficult to use your birth control properly when having sex.	1. True 2. False
You can change one primary form of birth control for another without talking with the doctor first.	1. True 2. False
You can use any forms of birth control for the iPLEDGE Program	1. True 2. False
You are using 2 effective forms of birth control in the month after your last dose. Your partner's condom breaks. You would:	1. Forget about it since you have finished isotretinoin 2. Call your doctor to see if you might need emergency birth control. 3. Get a home pregnancy test kit to see if you are pregnant.
While you are taking isotretinoin, you must use 2 effective forms of birth control together all the time	1. True 2. False
You should talk to your doctor about birth control:	1. Each month during your office visit. 2. Only when you have a problem. 3. Only when you sign the second consent form.
You have finished your last dose of isotretinoin. Your doctor has ordered a pregnancy test. For the next month, you:	1. Continue to use 2 effective forms of birth control together all the time. 2. Stop using your secondary form because you are not taking isotretinoin. 3. Go for the pregnancy test at any time during the month.

Birth Defects and Pregnancy	
Which of the following are signs you might be pregnant?	1. You miss your menstrual period
	2. You have nausea, sometimes referred to as morning sickness.
	3. Your breasts feel tender, like at the beginning of a menstrual period.
	4. Any of the above is a sign you might be pregnancy.
The risk for birth defects for a baby whose mother took isotretinoin is	1. So low that you do not have to worry.
	2. Low enough so you do not need birth control.
	3. Very high even if a woman takes a small amount of isotretinoin.
You cannot get pregnant if you have sex under water	1. True
	2. False
You can get pregnant any time and anywhere you have sex, particularly unprotected sex.	1. True
	2. False
You can get pregnant if you have not started having menstrual periods.	1. True
	2. False
Which of the following birth defects may be caused by isotretinoin?	1. No ears
	2. Heart problems
	3. Small jaw and misshaped head
	4. A child could have any or all of these birth defects.
You think you may be pregnant and you have taken isotretinoin. You would:	1. Not worry because it was only a few doses.
	2. Stop isotretinoin and call your doctor. Even the smallest amount of isotretinoin may cause birth defects.
It's okay to take isotretinoin when	1. You are using one effective form of birth control.
	2. You are using 2 effective forms of birth control all the time.
	3. You may be pregnant.
You cannot get pregnant if:	1. You never have sex with a man.
	2. You miss your hormone shots.
	3. You use only a condom with spermicide.

Safety Information	
I must not give blood while taking isotretinoin and 1 month after stopping isotretinoin.	1. True
	2. False
I will not share my isotretinoin with anyone.	1. Agree
	2. Disagree
Your neighbor wants to try your isotretinoin. You tell her or him:	1. I must not share isotretinoin.
	2. It might be harmful to her or him.
	3. You tell her or him both of these reasons.
The Red Cross calls you to give blood right after your last dose. You tell them:	1. I can never give blood again.
	2. I cannot give blood until 1 month after my last dose of isotretinoin.
The Red Cross calls you to give blood during your first month after your last dose. You tell them:	1. Giving blood is not safe for me.
	2. I cannot give blood until 1 month after my last dose of isotretinoin.
	3. I can never give blood again.

Obtaining a Prescription	
Your pharmacist can fill and dispense your prescription only after:	1. You phone it in.
	2. Checking with the iPLEDGE Program system to see if you can get isotretinoin.
	3. You email it in.
You can get a prescription for isotretinoin only if:	1. You pregnancy test is negative.
	2. You answered the questions correctly.
	3. You entered your 2 forms of birth control.
	4. Your doctor entered your 2 forms of birth control.
	5. All of these.
You had a pregnancy test on Tuesday for your next prescription. What is the last day you can obtain your prescription?	1. Later that same day (7 hours later)
	2. By Friday before the pharmacy closes
	3. On Monday of the next week
You can obtain your prescription any time you want	1. True
	2. False
Your doctor has entered your negative pregnancy test results and your two forms of birth control into the iPLEDGE Program system and gives you a prescription. Before you can obtain the prescription you must:	1. Answer your comprehension questions in the iPLEDGE Program system.
	2. Schedule your next appointment with your doctor
	3. Sign your informed consent each month.

Contraception Choices	
You missed 2 birth control pills earlier this week. You would:	1. Not have sex for the rest of the cycle, but keep taking the birth control pills as prescribed
	2. Have sex whenever you want.
I have been using birth control pills for 5 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail
	2. The birth defects are too severe to risk getting pregnant
	3. Isotretinoin may change how well some forms of birth control work
	4. All of these
Birth control pills work best when you take them every day as prescribed.	1. True
	2. False
You can switch to the progesterone-only mini-pill for your primary form of birth control while you are taking isotretinoin.	1. True
	2. False
Birth control pills may not work as well when you are taking isotretinoin. It is important to:	1. Take two birth control pills every day.
	2. Remember to take your birth control pill every day and always use a second effective method to help prevent pregnancy.
	3. Take your birth control pill only before having sex
I use my primary form of birth control exactly as prescribed and my partner uses condoms as the second form. My partner does not have any condoms with him tonight. We would:	1. Have sex anyway.
	2. Wait until he can buy a condom.
	3. Have sex but use withdrawal.
I use my primary form of birth control exactly as prescribed and my partner uses condoms with spermicide as the second form. My partner's condom breaks. I would:	1. Not worry about getting pregnant.
	2. Worry that I may become pregnant but not do anything.
	3. Call my doctor to talk about emergency birth control.
My partner has only one condom with him. We would:	1. Have sex more than once and reuse the condom.
	2. Have sex once and wait until he can buy more condoms.
	3. Have sex but use withdrawal.
For the iPLEDGE Program, condoms can be used with or without spermicide.	1. True
	2. False
If you use lubricant with a latex condom, it should be a water-based lubricant.	1. True
	2. False
Your partner should put his condom on:	1. Any time during sex.
	2. As soon as he gets an erection, because waiting too long lets sperm leak out.
	3. Only when he remembers.

You find a hole in your diaphragm after you had sex. You should:	1. Forget about it since you were near your period.
	2. Call your doctor to see if you might need emergency birth control.
For the iPLEDGE Program, diaphragms can be used with or without spermicide.	1. True
	2. False
After sex, your diaphragm should stay in place for:	1. 24 hours or more.
	2. 2 to 4 hours
	3. At least 6 hours and up to 24 hours.
You and your partner want to have sex a second time after you put in your diaphragm. You must:	1. Put spermicide in your vagina again before you have sex.
	2. Have sex again without using more spermicide for up to 24 hours at a time.
	3. Take out your diaphragm and clean it before having sex again.
Your gynecologist or family doctor needs to check how your diaphragm fits:	1. Every time you have sex.
	2. Every 2 years or if you gain or lose 10 pounds.
	3. Every 2 months.
The diaphragm with spermicide can help prevent:	1. Pregnancy
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
I use my primary form of birth control exactly as prescribed and a cervical cap with spermicide as my second form. I forgot my cap at home. I would:	1. Have sex anyway.
	2. Wait until I can use the cervical cap with spermicide.
	3. Have sex but use withdrawal.
For the iPLEDGE Program cervical caps can be used with or without spermicide.	1. True
	2. False
If you use a lubricant with your cervical cap, it should be a water-based lubricant.	1. True
	2. False
You find a hole in your cervical cap after you had sex. You should:	1. Forget about it since you were near your period.
	2. Call your doctor to see if you might need emergency birth control.
You and your partner want to have sex a second time after you put in your cervical cap. You do not need to put in more spermicide.	1. True
	2. False
After sex, your cervical cap should stay in place for:	1. 24 hours.
	2. 4 to 8 hours.
	3. At least 6 hours and up to 48 hours.

The cervical cap with spermicide can help prevent:	1. Pregnancy.
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
I use my primary form of birth control exactly as prescribed and use a vaginal sponge as my second form. I ran out of sponges tonight. My partner and I would:	1. Wait until I can buy more sponges or some other secondary form of birth control.
	2. Have sex anyway.
	3. Have sex but use withdrawal.
I use my primary form of birth control exactly as prescribed, but I forgot to put in my vaginal sponge this one time. I would:	1. Not worry that I could have gotten pregnant.
	2. Worry that I may become pregnant, but do nothing.
	3. Call my doctor to talk about emergency birth control.
The vaginal sponge can help prevent:	1. The spread of HIV (AIDS)
	2. The spread of other sexually transmitted infections (STIs)
	3. Pregnancy
You should insert your sponge:	1. Any time during sex.
	2. Any time up to 30 hours before you have sex.
	3. Only when you remember.
After sex, your sponge should stay in place for:	1. 24 hours or more.
	2. 2 to 4 hours.
	3. At least 6 hours.
If you and your partner want to have sex a second time after you put in your sponge:	1. You must put spermicide in your vagina again before you have sex.
	2. You can have sex again without using a new sponge for up to 30 hours at a time.
	3. You must take out your sponge and out in a new one before having sex.
I have been using the hormonal skin patch perfectly for over a year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
I have been using the hormonal skin patch, but I was 2 days late changing it. I would:	1. Not have sex for the rest of my cycle, but keep using the hormonal patch as prescribed.
	2. Have sex when I want to, my partner's condom is enough.

I am using the hormonal skin patch exactly as my doctor tells me. I should not put it on:	1. My upper outer arm.
	2. My stomach or upper body.
	3. My breasts.
The hormonal skin patch works best when you change it every week as prescribed.	1. True
	2. False
You can get pregnant using the hormonal patch if:	1. It becomes loose or falls off for more than 24 hours.
	2. You leave the same hormonal patch on more than one week.
	3. Both 1 and 2.
My hormonal vaginal ring slipped out and I did not replace it within 3 hours, I would:	1. Not have sex for the rest of my cycle, but keep using the hormonal vaginal ring as prescribed.
	2. Have sex when I want to, my partner's condom with spermicide is enough.
I have been using a hormonal vaginal ring for 1 year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
I am using the hormonal vaginal ring as my primary form. I can use it with which of the following barrier methods?	1. Cervical cap with spermicide.
	2. Condom with or without spermicide.
	3. Diaphragm with spermicide.
The hormonal ring works best when you change it on time every month, as prescribed.	1. True
	2. False
Pregnancy can happen when you are using a hormonal vaginal ring if:	1. The unopened package containing the hormonal vaginal ring is put into direct sunlight or gets hot.
	2. It slips out of your vagina and you do not replace it within 3 hours.
	3. It does not stay in your vagina for 3 weeks.
	4. You leave it in your vagina for more than 3 weeks.
	5. All of these reasons.

I have been getting hormone shots for 1 year and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
You get hormone shots:	1. Every 4 or 12 weeks, depending on the brand of the product.
	2. In your arm, belly, or buttocks.
	3. Both are true.
You are using hormonal shots as your primary form of birth control, you should remember:	1. You are not protected against HIV (AIDS)
	2. You need to see your doctor to get the hormonal shot
	3. They might delay your ability to get pregnant after you stop using hormonal shots.
	4. All of the above.
One advantage of hormone shots is that they also protect against sexually transmitted infections (STIs).	1. True
	2. False
You have chosen hormone shots as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
You have received a prescription for isotretinoin from your doctor but have not had the prescription filled. It is OK to have unprotected sex since you have had a negative pregnancy test.	1. True
	2. False
You check for the strings on your IUD, but cannot feel them. You would:	1. Not worry because you are also using a diaphragm with spermicide.
	2. Call your gynecologist.
I have been using an IUD for 3 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail.
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
Your IUD needs to be checked by your doctor:	1. Within 3 months after you had it inserted.
	2. If you can feel the strings.
	3. If your weight stays the same.

You have chosen an IUD as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
I had tubal sterilization (my tubes tied) 5 years ago and have not gotten pregnant. Why do I need another form of birth control now?	1. Any form of birth control can fail, including tubal sterilization (having my tubes tied).
	2. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is tubal sterilization (having my tubes tied). I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin:	1. True
	2. False
Important information to know about tubal sterilization (tying your tubes) is:	1. Tubal sterilization (tying your tubes) does not protect against sexually transmitted infections (STIs).
	2. Tubal sterilization (tying your tubes) does not require surgery.
	3. It is easy to re-open the tubes.
Tubal sterilization (tying your tubes) is a highly effective form of birth control and does not require use of another effective form of birth control while taking isotretinoin:	1. True
	2. False
You have chosen tubal sterilization (tying your tubes) as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
My only partner had a vasectomy 5 years ago and I have not gotten pregnant. Why do I need another form of birth control now?	1. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	2. Any form of birth control can fail.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is my only partner's vasectomy. I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin.	1. True
	2. False

Important information to know about your partner's vasectomy is:	1. Your partner's vasectomy does not protect against sexually transmitted infections (STIs).
	2. Your partner's vasectomy does not require surgery.
	3. It is easy to open the tubes again if your partner wants a child later.
Your partner's vasectomy is a highly effective form of birth control and does not require use of another effective form of birth control while taking isotretinoin:	1. True
	2. False
You have chosen your partner's vasectomy as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
I have had implanted hormones for 2 years and have not gotten pregnant. Why do I need another form of birth control now?	1. Using two forms of birth control all the time drastically reduces the chance that you will get pregnant.
	2. Any form of birth control can fail.
	3. Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control.
	4. All of these.
My primary form of birth control is implanted hormones. I also need to use a secondary form or another primary form of birth control while I am taking isotretinoin.	1. True
	2. False
My implantable hormone will only be effective through the first month while I am taking isotretinoin, after that I only need to use one effective form of birth control for the rest of my treatment.	1. True
	2. False
You have chosen implantable hormones as your primary method of birth control. Another acceptable form for you to use would be:	1. Female condoms
	2. IUD Progesterone T
	3. Withdrawal
	4. None of the above
Abstinence means no sex at all, 24 hours a day, 7 days a week.	1. True
	2. False
One of the most common causes of unplanned pregnancy is not being able to avoid sex.	1. True
	2. False

You planned not to have sex while taking isotretinoin, so you do not use any birth control. If you decide to have sex, you need to:	1. Work with your doctor to develop a plan to go on birth control before having sex.
	2. Stop having sex until you use your new birth control form for at least 1 month and have a negative pregnancy test.
	3. Start using three forms of effective birth control, just to be sure.
	4. 1 and 2 are correct.
Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.	1. True
	2. False
Important information to know about birth control pills is:	1. You cannot get pregnant while using birth control pills even if you skip pills.
	2. Birth control pills do not protect against sexually transmitted infections (STIs) or HIV (AIDS)
	3. There are no side effects from using birth control pills.
The male condom can help prevent:	1. Pregnancy.
	2. The spread of HIV (AIDS)
	3. The spread of other sexually transmitted infections (STIs)
	4. All of the above.
For 1 month after your last dose, you must use 2 effective forms of birth control together all the time.	1. True
	2. False

[Name of Manufacturer]

{Product Name and Generic Designation} Wholesaler to Wholesaler Shipment Request Form

REQUESTING PARTY INFORMATION: (Please print or type)

Requester Name: _____Telephone: _____

E-Mail Address: _____ Date of Request: _____

Wholesaler Name: _____ DEA: _____

Address: _____City:_____State:_____Zip:_____

Requesting Party represents and warrants that the Receiving Party listed below is registered with the iPLEDGE Program.

Requester Signature: _____ Date: _____

RECEIVING PARTY INFORMATION

Wholesaler Name: _____ DEA: _____

Address: _____City:_____State:_____Zip:_____

Ship to Address: _____City: _____State: _____Zip: _____

MANUFACTURER'S CONSENT

Shipments of [Product Name and Generic Designation] between wholesalers* must be in compliance with the iPLEDGE Program. Labeling for [Product Name] states that wholesalers registered in the iPLEDGE Program may only ship to other registered wholesalers with prior written consent from the manufacturer. Pursuant to the labeling for [Product Name], the authorized signature below shall serve as written consent from the manufacturer provided that the requesting and receiving party's registration is verified prior to each shipment. Registration will be verified by [Manufacturer Name] upon receipt of shipment request.

**The term wholesaler refers to a wholesaler and each of its individual distribution centers, a distributor and each of its individual distribution centers, and/or each warehousing chain pharmacy distribution center.*

[Name of Manufacturer]

By: _____Title: _____

Print Name: _____Date: _____

Please return completed forms to [Insert Appropriate Information Including Fax Number, Email URL, Telephone Number, etc.]

Please note that this approval is for a one time shipment. Further shipments require consent from [Manufacturer].

iPLEDGE™
Committed to Pregnancy Prevention

Wholesaler Registration Letter

Dear wholesaler or chain drug executive,

The iPLEDGE Program requires annual registration of all wholesalers distributing isotretinoin. For the purposes of the iPLEDGE Program, the term wholesaler refers to a wholesaler and each of its individual distribution centers, a distributor and each of its individual distribution centers, and/or each warehousing chain pharmacy distribution center.

A Registration Form is enclosed with this letter.

Key Elements of the iPLEDGE Program, Which Relate to Your Business Practices:

- The program covers all isotretinoin products (brand and generic)
- To be registered, each wholesaler must agree to meet all iPLEDGE requirements for wholesale distribution of isotretinoin products by completing the enclosed agreement
- Wholesalers registered in the iPLEDGE Program will only ship isotretinoin to:
  - Wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer, or
  - Pharmacies registered with and activated in the iPLEDGE Program
- The registration of wholesalers that do not abide by the terms of the agreement will be revoked after an investigation process, and manufacturers of FDA-approved isotretinoin products will not continue to provide them with isotretinoin for distribution
- Registration in the iPLEDGE Program expires in 12 months and requires re-registration annually.

To Register in the iPLEDGE Program, Mail the Completed Agreement to:

iPLEDGE Program
P.O. Box 29094
Phoenix, AZ 85038

OR

Fax the completed form, using the following iPLEDGE fax number: 1-866-495-0660

We thank you for your support in complying with the iPLEDGE Program.

Sincerely,

Karin Greenberg, Pharm.D., BCPS
Sr. Director and Global Head of Pharmacovigilance
Dr. Reddy's Laboratories, Inc.

Eric H. Davis, M.D.
Director, Medical Services
Global Product Safety & Risk Management
Mylan Pharmaceuticals

Ashish Anvekar
Senior Director, Brand
Ranbaxy Laboratories, Inc.

Kishore Gopu
Director, REMS
Teva Pharmaceuticals USA

John Franolic, Ph.D.
Vice President of Regulatory Affairs
VersaPharm Incorporated

Reference ID: 3956479

iPLEDGE™
Committed to Pregnancy Prevention

Wholesaler Registration (continued)

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE ™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors, or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

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Committed to Pregnancy Prevention

iPLEDGE Program
P.O. Box 29094
Phoenix, AZ 85038

Wholesaler Registration Form On Behalf of the Wholesaler Listed Below, I Acknowledge That:

For the purpose of the iPLEDGE Program, the term wholesaler refers to a wholesaler and each of its individual distribution centers, a distributor and each of its individual distribution centers, and/or each warehousing chain pharmacy distribution center. To distribute isotretinoin, wholesalers must be registered with the iPLEDGE Program and agree to meet all iPLEDGE Program requirements for wholesaler distribution of isotretinoin products. Wholesalers must register with the iPLEDGE Program by signing and returning this agreement that affirms they will comply with all iPLEDGE Program requirements for distribution of isotretinoin. The registration of wholesalers that do not abide by the terms of the agreement will be revoked after an investigation process, and manufacturers of FDA approved isotretinoin products will not continue to provide them with isotretinoin for distribution. Each distribution center operated by a wholesaler must register if they are to distribute isotretinoin. These requirements include:

- Registering prior to distributing isotretinoin and registering annually thereafter
- Distributing only FDA approved isotretinoin product obtained directly from the isotretinoin manufacturers (or delegate) or another registered wholesaler
- Beginning November 1, 2005 only ship isotretinoin to:
  - Wholesalers registered in the iPLEDGE Program with prior written consent from the manufacturer, or
  - Pharmacies licensed in the US and registered and activated in the iPLEDGE Program
- Notifying immediately the isotretinoin manufacturer (or delegate) of any nonregistered and/or nonactivated pharmacy or unregistered wholesaler that attempts to order isotretinoin
- Complying with inspection of wholesaler records by the isotretinoin manufacturer (or delegate) for verification of compliance with the iPLEDGE Program
- Returning to the manufacturer (or delegate) any undistributed product if registration is revoked by the iPLEDGE Program or if the wholesaler chooses to not reregister annually.

An agreement must be completed for each distributor center.

I am authorized to execute this agreement on behalf of the wholesaler (and its distribution centers, if applicable)

Wholesaler Name _____

iPLEDGE™
Committed to Pregnancy Prevention

(Type or Print)

Distribution Center's DEA# _____

Distribution Center's Address _____

Distribution Center's City _____

Distribution Center's State _____ Distribution Center's ZIP _____

Distribution Center's Phone Number _____

Distribution Center's Fax Number _____

Authorized Representative _____
(Print First, MI, Last)

Title _____

E-mail Address for Key Contact _____

E-mail Address for Pharmacy Eligibility File Delivery*_____

Authorized Representative's Signature _____

Date _____/_____/_____
Month Day Year

*The list of registered and activated pharmacies will be e-mailed to this address daily.

This agreement expires 12 months from agreement date. Annual registration is required.

www ipledgeprogram.com | 1-866-495-0654

Wholesaler Product Return Letter

Isotretinoin Return Customer Instruction Guide - Wholesaler

Wholesaler Name
Address 1
Address 2
City, State Postal Code

Dear Wholesaler:

You are no longer registered in the iPLEDGE Program for the following reason:

- Your facility is closing, and will no longer be a wholesaler in the iPLEDGE Program.

Therefore, you are required to return all isotretinoin inventories in stock **effective immediately**.

This action is pursuant to the FDA approval of the iPLEDGE Program through the special restricted distribution program. If you have questions about your status in the iPLEDGE Program, please call 1-866-495-0654 or visit www.ipledgeprogram.com for more information.

Action required by a wholesaler no longer registered in the iPLEDGE Program:

- Immediately remove all isotretinoin from your stock.
- If you have isotretinoin inventory, please call **1-866-495-0654** for further instructions on returning this product to the manufacturer.

Sincerely,

iPLEDGE Program

Wholesaler Product Return Letter (continued)

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

iPLEDGE, an enhanced pregnancy risk management program designed to minimize fetal exposure to isotretinoin, has been approved by the FDA through a special restricted distribution program

FDA REMS Submission

Prescriber Screens Inventory

iPLEDGE Program

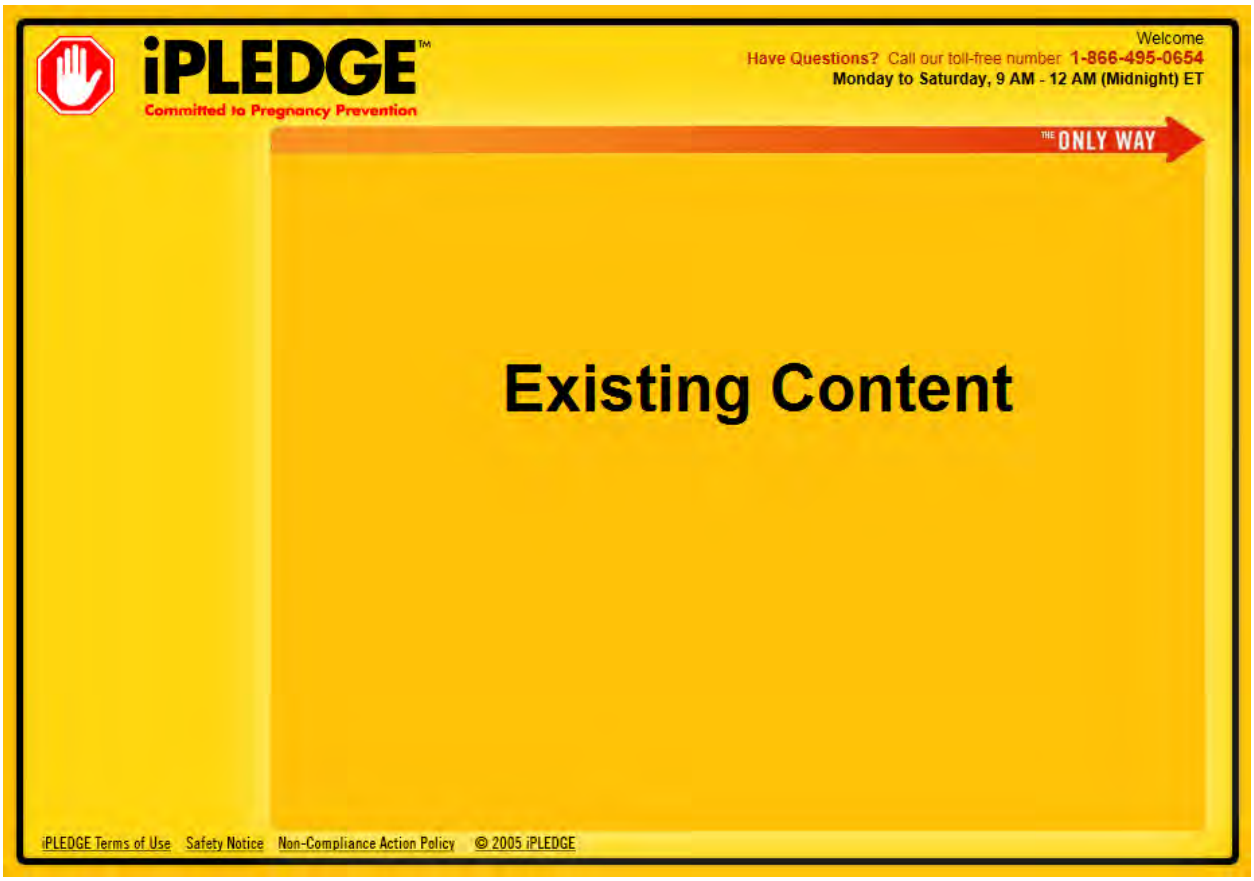
Revised: May 2016

Prescriber Screens Inventory:

- Common – Header and Footer
- Prescriber Registration – from Prescriber Home Page
- Prescriber Home Page
- Prescriber Home Page (Alternate)
- Prescriber Activation
- Register New Patient
  - FRP
  - FNRP
    - Confirm FNRP
  - MALE
    - Confirm MALE
- About Isotretinoin
- About iPLEDGE
- Manage Patients
  - Program Status Descriptions by Patient Type (info button)
  - Edit Patient Demographics Button
  - Confirm Patient Counseling Button – FRP/FNRP
  - Edit Patient Contraception Button
  - Post-therapy Pregnancy Test Button
  - Check Patient Status Button – FRP/FNRP
  - Re-Register Patient Button
    - FRP
    - FNRP
    - MALE
  - Change Patient Type Button
    - FRP
    - FNRP
  - Discontinue Patient Button
  - Report Pregnancy Button
- Prescriber Information
- Order Materials
- Update My Information
  - Edit Prescriber Demographics
  - Change DOPS
  - Change Password
- Accept Patient
- Manage Delegates/Designees
- My Program Status
- Find a Participating Pharmacy
- FAQs/How To's
- Action Required List
- Terms of Use
- Safety Notice

UBC
Reference ID: 3956479

Common – iPLEDGE Web page header/footer



UBC
Reference ID: 3956479

Prescriber Registration – For Prescribers (Button) from Public Home Page

iPLEDGE™
Committed to Pregnancy Prevention

Welcome
Have Questions? Call our toll-free number 1-866-495-0654
VLWeb01/PROD: Monday to Saturday, 9 AM - 12 AM (Midnight) ET

™ONLY WAY

HOME
PATIENT INFORMATION
ABOUT ISOTRETINOIN
ABOUT iPLEDGE
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Prescriber Registration

Attention: This registration page is for licensed prescribers only. If you are a patient, you must be registered in iPLEDGE by your doctor.

Please provide your DEA number. This will be used as your Username to identify you in the program and for you to login to the iPLEDGE system using the phone or Internet site. The DEA number provided must be your DEA number, not an institutional or shared DEA number. Please provide only one DEA number if you have more than one.

If you do not have a DEA number, check the box indicating that you would like the program to generate a Username to be used to identify you in the program. This program generated Username will be shipped to you in your prescriber educational kit.

DEA Number _____ or ☐ Generate Username

Enter or confirm your information

* denotes required field

First Name* | Last Name* | MI | Suffix MD | Specialty

Address*

City* | State* | Zip*

Phone* | Fax

Email

Preferred Method of Communication*

Select delegates

DEA Number or Username | Delegate List

Add

Expiration Date (MM/DD/YYYY)

Remove

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

Save and Print

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UBC
Reference ID: 3956479

Prescriber Home Page – Activated Prescriber not within 30 days of expiration.

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Welcome iPLEDGE Prescriber
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SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Manage Patients

Manage Patients

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
If you are reporting a pregnancy from a monthly pregnancy test, please use the pregnancy test results page under "Manage Patients."

Toll free number: 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET

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Prescriber Home Page – Prescriber in Program Status "Registered" or activated Prescriber whose activation expires within 30 days.

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Activate My Registration

Follow the program steps to activate your registration. Remember: you must activate your registration in the iPLEDGE Program annually. Please click the Activate button below to begin.

Activate

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
To report a pregnancy, please call: 1-866-495-0654

Toll free number: 1-866-495-0654 Monday to Saturday, 9 AM - 12 AM (Midnight) ET

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Prescriber Activation

Prescribers can only activate their registration by affirming that they meet requirements and will comply with all iPLEDGE requirements by attesting to the following points:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I know the risk factors for unplanned pregnancy and the effective measures for avoidance of unplanned pregnancy.
- I have the expertise to provide the patient with detailed pregnancy prevention counseling or I will refer her to an expert for such counseling, reimbursed by the manufacturer.
- I will comply with the iPLEDGE Program requirements described in the booklets entitled The Guide to Best Practices for the iPLEDGE Program and The iPLEDGE Program Prescriber Contraception Counseling Guide.
- Before beginning treatment of female patients of childbearing potential with isotretinoin and on a monthly basis, the patient will be counseled to avoid pregnancy by using two forms of contraception simultaneously and continuously one month before, during, and one month after isotretinoin therapy, unless the patient commits to continuous abstinence.
- I will not prescribe isotretinoin to any female patient of childbearing potential until verifying she has a negative screening pregnancy test and monthly negative CLIA-certified (Clinical Laboratory Improvement Amendment) pregnancy tests. Patients should have a pregnancy test at the completion of the entire course of isotretinoin and another pregnancy test 1 month later.
- I will report any pregnancy case that I become aware of while the female patient is on isotretinoin or 1 month after the last dose to the pregnancy registry.

○ I attest to the statements above.
○ I do not attest to the statements above.

Cancel Continue

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Prescriber - Prescriber Activation - Compliance Notice

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Prescriber Activation

Compliance Notice

Isotretinoin is teratogenic and must not be used by pregnant women. The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. With these program goals in mind, iPLEDGE data is routinely analyzed to identify actions of non-compliance.

Information entered into the iPLEDGE system is considered part of the patient's medical record, and can be used to investigate suspected non-compliance. Verified non-compliance with regard to the iPLEDGE Program requirements can result in removal from the iPLEDGE Program.

Prescribers are responsible for all iPLEDGE activities performed by their Office Staff Designees. If an Office Staff Designee is found to be non-compliant with iPLEDGE, resulting actions, including possible removal from the iPLEDGE Program, can include both the Designee and the Prescriber.

Verified non-compliance may be reported to the FDA.

- I acknowledge the statements above.
- I do not acknowledge the statements above.

Back Submit

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Prescriber - Prescriber Activation Complete

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Prescriber Activation Complete

You are now activated in the system.
You may now select any of the menu options to the left to begin using the system.

Current Program Status: Attested
Status Expires: 5/28/2016

Finish

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- (•) Patient is a Female of Reproductive Potential (FRP)
- ( ) Patient is a Female NOT of Reproductive Potential (FNRP)
- ( ) Patient is Male

Continue Cancel

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Prescriber - Register New Patient – FRP

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Enter In-Office Pregnancy Test Results:

** denotes required field*

In-Office Pregnancy Test Result:

- In-Office Pregnancy Test is Positive
- In-Office Pregnancy Test is Negative

Date of In-Office Positive or Negative Pregnancy Test (MM/DD/YYYY)*

Continue | Cancel

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Register New Patient

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Enter Patient Information:

** denotes required field*

First Name* Last Name* Middle Initial

Address*

City* State* ZIP*

Continue Cancel

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Prescriber - Register New Patient – FRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for iPledge Patient - continued:

** denotes required field*

Phone Number*
Email

Date of Birth (MM/DD/YYYY)*
Last Four Digits of Social Security Number*

☐ Check this box if the patient doesn't have a social security number.

Preferred Method of Communication*

☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – FRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

iPledge Patient
123 Test Drive
Blue Bell, PA 18754-4578

Phone Number: 5555551212
Email: test@aol.com

Preferred Method of Communication:
Email

Date of Birth: 4/18/1977
Last Four Digits of Social Security Number: 1977

I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – FRP – Patient not unique

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Register New Patient

Category | Review | Pregnancy Result | Parenteral | Uniqueness | Identification Number | Finish

This patient may not be unique.
Please contact the Call Center at 1-866-495-0654 to obtain an override code.

You may need the patient information below to assist the Call Center Representative in determining patient uniqueness.

John Smith
123 Blue Moon St
Blue Bell, PA 19422

Date of Birth:	Last Four Digits of Social Security Number:
4/18/1997	1234

Please Enter Override Code

Continue Cancel

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Prescriber - Register New Patient – FRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Consent | Identification Number | Finish

Enter Patient Identification Number for iPledge Patient:

** denotes required field*

Please find the patient identification number from the patient education materials, and enter it below.

Patient Identification Number *

Patient Identification Number (Type Again) *

Continue Cancel

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Prescriber - Register New Patient – FRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Finish

Patient Registration is complete for iPledge Patient.
A password will be mailed to the patient, and should be received within 5 to 10 days.

This patient has a 30 day wait period before she can be confirmed. This 30 day wait period begins on the date of registration. You may confirm this patient on or after 6/27/2015.

Do not give the patient a prescription to fill until after you provide this confirmation.

Finish

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Prescriber – Register New Patient - FNRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)
- Patient is Male

Continue Cancel

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Prescriber - Register New Patient – FNRP – Acknowledgement

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Determine Patient Category:

You have indicated that this patient is a female. The questions that follow will assign a risk category to this female patient, based on her reproductive potential according to the requirements of the iPLEDGE Program.

All female patients are considered Female of Reproductive Potential (FRP) unless one or more of the following applies:

1. Patient has had a hysterectomy
2. Patient has had a bi-lateral oophorectomy
3. Patient is post-menopausal

Please note that the following conditions DO NOT qualify a patient to be moved from the FRP risk category.

- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please acknowledge your understanding of the qualification criteria as presented to proceed with assigning a risk category to this patient.

I Acknowledge | Cancel

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Prescriber - Register New Patient – FNRP – Determine Patient Category Question 1 of 3

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Determine Patient Category:

Has patient had a hysterectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Register New Patient – FNRP – Determine Patient Category Question 2 of 3

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Determine Patient Category:

Has patient had a bi-lateral oophorectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Register New Patient – FNRP – Determine Patient Category Question 3 of 3

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

For the iPLEDGE Program, a woman is considered post-menopausal upon cessation of previously occurring menses as a result of ovarian failure with documentation of hormonal deficiency by a certified healthcare provider. (i.e. spontaneous menopause)

Hormonal deficiency should be properly documented in the case of spontaneous menopause as follows:

1. If age > 54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed.

2. If age < 54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

Using the definition above, is this patient post-menopausal?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FNRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female of NON-Reproductive Potential (FNRP)**

Based on the following criteria:

Is patient Male?	No
Has patient had a hysterectomy?	**Yes**
Has patient had a bi-lateral oophorectomy?	**Yes**
Is this patient post-menopausal?	**Yes**

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

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Prescriber - Register New Patient – FNRP – Patient Information

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Enter Patient Information:

** denotes required field*

First Name* Last Name* Middle Initial

Address*

City* State* ZIP*

Continue Cancel

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Prescriber - Register New Patient – FNRP – Patient Information

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Test Patient - continued:

** denotes required field*

Phone Number*
Email

Date of Birth (MM/DD/YYYY)*
Last Four Digits of Social Security Number*

☐ Check this box if the patient doesn't have a social security number.

Preferred Method of Communication*

☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – FNRP – Patient Information Review

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Test Patient
123 Test Street
Blue Bell, PA 12457

Phone Number: 123-555-1212
Email: Not provided

Preferred Method of Communication:
U.S. Mail

Date of Birth: 6/6/1966
Last Four Digits of Social Security Number: 9076

I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – FNRP – Patient Identification Number

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Identification Number for Test Patient:

** denotes required field*

Please find the patient identification number from the patient education materials, and enter it below.

Patient Identification Number *

Patient Identification Number (Type Again) *

Continue Cancel

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Prescriber - Register New Patient – FNRP – Finish

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Unknowns | Finish

Patient Registration is complete for Test I Patient.
A password will be mailed to the patient, and should be received within 5 to 10 days.

Before Test I Patient can fill a prescription, you must confirm patient counseling in the system.
Please click the Continue button below to start the confirmation process.

Continue

Otherwise select the Finish button below to complete Test I Patient's registration.
Note: you may confirm Test I Patient at a later date using the Manage Patients screen.

Finish

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Prescriber - Register New Patient – FNRP – Continue option to confirm FNRP

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3306061966
First Name: FNRP
Last Name: Patient
Date of Birth: 06/06/1966

☐ I have counseled this patient on the following:

- Drug should not be shared with anyone
- Blood should not be donated while taking isotretinoin
- Patient program requirements

☐ Check this box if this is the patient's last month of treatment.

○ Yes ○ No In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.

Selecting the "Continue" button confirms that you have provided the monthly counseling to this patient.

Continue Cancel
Please click button only once.

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Prescriber - Register New Patient – FNRP – Confirm FNRP complete

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Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Confirm | Contraception | Pregnancy Test | Finish

Identification Number:	3306061966
First Name:	FNRP
Last Name:	Patient
Date of Birth:	06/06/1966

Confirm Patient Counseling is Complete.
The patient's Program Status is **Qualified to Receive Drug**.
The patient may pick up their prescription at the pharmacy. The patient must pick up the prescription before 11:59 PM Eastern Time on 6/30/2015.

Finish

Please click button only once.

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Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FRP

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female of Reproductive Potential (FRP)**

Based on the following criteria:

Is patient Male?	No
Has patient had a hysterectomy?	No
Has patient had a bi-lateral oophorectomy?	No
Is this patient post-menopausal?	No

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.
If your responses are correct, but you still believe this patient to be a Female of NON-Reproductive Potential, click Request FNRP Status.

Back | Continue | Request FNRP Status

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Prescriber - Register New Patient – FNRP – Request FNRP Status

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Notice!
Your responses indicate that this patient should be registered as a Female of Reproductive Potential (FRP). However you are requesting to register this patient as a Female NOT of Reproductive Potential (FNRP). **This must be due to an unusual circumstance or unique medical condition not covered in the definition of FNRP for the iPLEDGE Program.**

The following **are not** reasons to register a patient as an FNRP, **and requests based on these reasons will be denied.**
- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please contact the Call Center at 1-866-495-0654 to provide further information. You may be required to provide documentation to support this request.

If this request is denied, the patient will need to be re-registered after a negative pregnancy test. Isotretinoin therapy can only begin 30 days from the date the patient is re-registered.

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Prescriber - Register New Patient – MALE

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)
- Patient is Male

Continue Cancel

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Prescriber - Register New Patient – MALE – Patient Information

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Register New Patient

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Enter Patient Information:

** denotes required field*

First Name* Last Name* Middle Initial

Address*

City* State* ZIP*

Continue Cancel

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Prescriber - Register New Patient – MALE – Patient Information

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Male Patient - continued:

** denotes required field*

Phone Number*
Email

Date of Birth (MM/DD/YYYY)*
Last Four Digits of Social Security Number*

☐ Check this box if the patient doesn't have a social security number.

Preferred Method of Communication*

☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – MALE – Patient Information Review

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Male Patient
123 Test Drive
Suite 123
Blue Bell, PA 15478

Phone Number: 215-555-1212
Email: malepat@yohoo.com

Preferred Method of Communication:
Email

Date of Birth: 7/7/1977
Last Four Digits of Social Security Number: Not provided

I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Register New Patient – MALE – Patient Uniqueness – Override Code

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Register New Patient

Category | Review | Pregnancy Result | Personal Info | Uniqueness | Identification Number | Finish

This patient may not be unique.
Please contact the Call Center at 1-866-495-0654 to obtain an override code.

You may need the patient information below to assist the Call Center Representative in determining patient uniqueness.

John Smith
123 Blue Moon St
Blue Bell, PA 19422

Date of Birth:	Last Four Digits of Social Security Number:
4/18/1997	1234

Please Enter Override Code

Continue Cancel

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Prescriber - Register New Patient – MALE – Identification Number Entry

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uncovered | Identification Number | Finish

Enter Patient Identification Number for Male Patient:

** denotes required field*

Please find the patient identification number from the patient education materials, and enter it below.

Patient Identification Number *

Patient Identification Number (Type Again) *

Continue Cancel

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Prescriber - Register New Patient – MALE – Finish

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Finish

Patient Registration is complete for Male Patient.
A password will be mailed to the patient, and should be received within 5 to 10 days.

Before Male Patient can fill a prescription, you must confirm patient counseling in the system. Please click the Continue button below to start the confirmation process.

Continue

Otherwise select the Finish button below to complete Male Patient's registration.
Note: you may confirm Male Patient at a later date using the Manage Patients screen.

Finish

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Prescriber - Register New Patient – MALE – Continue to Confirm after Finish

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number:	3307071977
First Name:	Male
Last Name:	Patient
Date of Birth:	07/07/1977

☐ I have counseled this patient on the following:

- Drug should not be shared with anyone
- Blood should not be donated while taking isotretinoin
- Patient program requirements

☐ Check this box if this is the patient's last month of treatment.

○ Yes ○ No In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.

Selecting the "Continue" button confirms that you have provided the monthly counseling to this patient.

Continue Cancel

Please click button only once.

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Prescriber - Register New Patient – MALE – Confirm complete

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Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Confirm | Contraception | Pregnancy Test | Finish

Identification Number:	3307071977
First Name:	Male
Last Name:	Patient
Date of Birth:	07/07/1977

Confirm Patient Counseling is Complete.
The patient's Program Status is **Qualified to Receive Drug**.
The patient may obtain their prescription at the pharmacy. The patient must obtain the prescription before 11:59 PM Eastern Time on 6/30/2015.

Finish

Please click button only once.

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Prescriber – About Isotretinoin

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About Isotretinoin

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

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About iPLEDGE

The iPLEDGE Program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a **SINGLE** pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPLEDGE Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of childbearing potential. The iPLEDGE Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPLEDGE system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mIU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

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Prescriber - Manage Patients

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Manage Patients

Search by Last Name: Search Clear

Include Past Patients in search

Select the radio button next to each Patient, then select an action from the buttons found below this table.

	Name	Identification	Date of Birth	FRP	Status	Address
◉	Patient, FCBP	3911101993	11/10/1993	Yes	Registered	123 Test Test
○	Patient, Female	3304041914	04/04/1914	No	Qualified to Receive Drug	123 Test Drive Blue Bell
○	Patient, Female	3304181997	04/18/1997	Yes	Required to Demonstrate Comprehension	123 Blue Moon St. Blue Bell
○	Patient, iPLEDGE	3011111992	11/11/1992	Yes	Confirmed Positive	123 Test Testing
○	Patient, iPledge	3104181997	04/18/1997	Yes	Registered	123 Test Drive Blue Bell
○	Patient, iPledge	3301011991	01/01/1991	Yes	Qualified to Receive Drug	123 Test Street Blue Bell
○	Patient, iPledge	3304181974	04/18/1977	Yes	Registered	123 Test Drive Blue Bell
○	Patient, iPLEDGE	3306061966	06/06/1966	Yes	Registered	123 FNRP Street Blue Bell

1 2

Select Action:

Edit Patient Demographics	Check Patient Status	Discontinue Patient
Confirm Patient Counseling	Re-Register Patient	Report Pregnancy
Edit Patient Contraception	Change Patient Type	Request Exemption
Post-therapy Pregnancy Test	Report Tanner Stage Change	

If you select a patient, and one of the action buttons is disabled, this is because either you or your patient is not in the required iPLEDGE Program status and the action is not allowed in that status.

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Prescriber - Manage Patients – Request Exemption button

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Exemption for Female Patients With Serious Medical Reasons

Exemption Option 1 - Tanner Stage 1 or 2

By selecting this option I attest that all of the following apply to this patient:

- Classified as Tanner Stage 1 or 2
- Not considered to be of reproductive potential
- Not currently pregnant
- I will evaluate this patient's reproductive status while receiving isotretinoin and I will notify the iPLEDGE Program within 10 business days of any change in the patient's reproductive status

Exemption Option 2 - Expedite Start of Treatment

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that she be exempt from the initial wait period
- Not currently pregnant
- Required to take monthly pregnancy tests
- Required to successfully complete monthly comprehension testing
- I understand that the patient will have 7 days to fill her prescription from the date of the monthly pregnancy test specimen collection

Exemption Option 3 - Cognitively and/or Physically Impaired

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that she be exempt from the initial wait period and the monthly comprehension testing
- Not currently pregnant
- Required to take monthly pregnancy tests
- I understand that the patient will have 7 days to fill her prescription from the date of the monthly pregnancy test specimen collection

Continue Cancel

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Prescriber - Manage Patients – Request Exemption Option Selected

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Exemption for Female Patients With Serious Medical Reasons

Notice!

The intent of this form is to request an exemption from the iPLEDGE requirements for a non-pregnant patient with serious medical reason(s) who is unable to obtain an isotretinoin prescription by completing the requirements in the iPLEDGE Program at this time. It is **NOT** intended to replace the requirements of the iPLEDGE Program.

Please make certain that you maintain medical documentation supporting the reason(s) for this exemption. The iPLEDGE Program may require a copy.

The medical exemption process is governed by the iPLEDGE Non-Compliance Action Policy. **Intentional misuse of the medical exemption process may result in Permanent Deactivation from the iPLEDGE Program resulting in a permanent loss of isotretinoin prescribing privilege.**

I attest that I am both qualified and have performed the necessary medical evaluation(s) to determine that the medical exemption is appropriate for this patient based on the iPLEDGE requirements.

Electronic Signature

X

Please type your first and last name exactly as it is shown here <insert of DB name> in the signature box to attach your legally binding electronic signature to this exemption request

Cancel Confirm

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Prescriber - Manage Patients – Report Tanner Stage Change button

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Tanner Stage 1 or 2 Classification Change Notification

Tanner Stage 1 or 2 Classification Change Notification

[X] This patent has now advanced beyond Tanner Stage 2 and all of the following apply to this patient:

- Considered to be of reproductive potential
- Not currently pregnant
- **Now required** to take monthly pregnancy tests
- **Now required** to successfully complete monthly comprehension testing
- I understand that the patient will have 7 days to fill her prescription from the date of the monthly pregnancy test specimen collection

Continue | Cancel

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Prescriber - Manage Patients – Status Column – Red info button - SAMPLE

Program Status Descriptions by Patient Type

Female Patients of Reproductive Potential

Registered

This is a patient who has been entered (registered) into the system by an activated prescriber. The patient will remain in this status for 1 month while she uses her two chosen forms of effective contraception before she can start the qualification process for a prescription.

or

This patient did not fill and pick up her prescription in her first 7-day prescription window, and must now wait a minimum of 19 days between pregnancy tests (with the second pregnancy test in the first 5 days of her menstrual cycle).

or

This patient was using abstinence to meet the requirements of iPLEDGE, but will now be using two other forms of contraception. This patient must be on the new forms of contraception for 30 days before she can get her next prescription.

or

This patient's risk category was previously changed from female of non-childbearing potential, but is still waiting for entry of an initial pregnancy test.

or

A patient that was determined to be a female of childbearing potential during the registration process, but there is a pending request to assign a risk category of female of non-childbearing potential due to special medical circumstances.

Required Action

After the required number of days (30 days if the patient was newly registered, or at least 19 days between pregnancy tests if she did not fill and pick up a prescription in her first 7-day prescription window), the prescriber must confirm the monthly counseling of the patient and enter pregnancy test results for the patient using the Confirm Patient Counseling feature on the Manage Patient screen or through the automated phone system. Entering the pregnancy test results begins the 7-day prescription window for prescription filling and dispensing, meaning the prescription must be filled and picked up within 7 days of the specimen draw date for the pregnancy test. Upon confirmation of the monthly counseling and entry of the pregnancy test results, the patient's status will change to "Required to Demonstrate Comprehension". If the registration is pending review for requested female of non-childbearing potential status, this patient cannot be confirmed until the request is reviewed and accepted through discussion with the iPLEDGE Call Center.

Requires Confirmation

This is a patient who has filled a prescription and is eligible to begin the requirements to fill another month's prescription

or

A patient whose 7-day prescription window expired before completing all program requirements or filling her prescription. This patient must fulfill all program requirements to fill another prescription.

Male Patients and Female Patients of Non-Reproductive Potential

Registered

A patient who has been entered into the system by an activated prescriber

Required Action

The prescriber must confirm the monthly counseling of the patient using the Confirm Patient Counseling feature on the Manage Patient screen or through the automated phone system. Confirmation of the monthly counseling begins the 30-day prescription window for prescription filling and dispensing, meaning the prescription must be filled and picked up within 30 days of the date the prescriber confirmed the monthly counseling of the patient. Upon confirmation of the monthly counseling, the patient's status will change to "Qualified to Receive Drug".

Requires Confirmation

A patient who has filled a prescription

or

A patient whose 30-day prescription window expired before completing all program requirements or filling and picking up his or her prescription.

Required Action

The prescriber must confirm the monthly counseling of the patient using the Confirm Patient Counseling feature on the Manage Patient screen or through the automated phone system. Confirmation of the monthly counseling begins the 30-day prescription window for prescription filling and dispensing, meaning the prescription must be filled and picked up within 30 days of the date the prescriber confirmed the monthly counseling of the patient. Upon confirmation of the monthly counseling, the patient's status will change to "Qualified to Receive Drug".

Qualified to Receive Drug

The prescriber and patient have completed all monthly requirements and the patient is qualified to have his or her prescription filled and picked up. The patient must obtain the prescription within the 30-day window which started on the date the prescriber confirmed the monthly counseling.

Required Action

Patient must obtain the prescription within at a pharmacy licensed in the U.S. and registered and activated in the iPLEDGE Program within 30 days of the date the prescriber confirmed his or her monthly counseling in the system.

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Prescriber - Manage Patients – Edit Patient Demographics Button

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Update Patient Contact Information

Use this form to edit the Patient's contact information. To edit information not displayed on this form, please contact the Call Center.

** denotes required field*

First Name*: FCBP
Last Name*: Patient
Middle Initial:
Address*: 123 Blue Moon St.
City*: Blue Bell
State*: PA
Zip*: 19854
Phone Number*: 555-555-1212
Date of Birth* (MM/DD/YYYY): 4/18/1997

Cancel | Save Changes

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Confirm

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number:	3304181997
First Name:	Female
Last Name:	Patient
Date of Birth:	04/18/1997

☐ I have obtained a signed female consent form for this patient.

☐ I have counseled this patient on the following:

- Requirement to use two forms of contraception every time they have intercourse
- Drug should not be shared with anyone
- Blood should not be donated while taking isotretinoin
- Patient program requirements

☐ Check this box if this is the patient's last month of treatment.

○ Yes ○ No In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.

Selecting the "Continue" button confirms that you have provided the monthly counseling to this patient.

Continue Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Contraception

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3304181997
First Name: Female
Last Name: Patient
Date of Birth: 04/18/1997

Please enter the forms of contraception:

Primary:

Barrier/Primary:

I have provided Contraception Counseling to this patient

Date Contraception Counseling was provided: / /

or

This patient was referred to and obtained Contraception Counseling from another Health Care Provider

Date Contraception Counseling was provided: / /

Back | Continue | Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Abstinence selected as Primary – Message

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3304181997
First Name: Female
Last Name: Patient
Date of Birth: 04/18/1997

Please enter the forms of contraception:

Primary: Abstinence

Barrier/Primary: None

More Information

Abstinence means that the patient will not have sex or sexual physical contact with any male 24 hours a day, 7 days a week. This can be hard to do. It is not a recommended way to prevent pregnancy for the iPLEDGE Program. One of the most common causes of unplanned pregnancy is failing to maintain abstinence (not being able to avoid sex).

If the patient cannot commit completely to not having sex while taking isotretinoin and for 1 month after therapy, she must use 2 separate, effective forms of birth control at the same time. She must choose forms of birth control that she will actually use all the time. Isotretinoin is not recommended if the patient cannot follow the birth control requirements of the iPLEDGE Program.

Back | Continue | Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Abstinence selected as Primary – Confirmation of Important Message

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3304181997
First Name: Female
Last Name: Patient
Date of Birth: 04/18/1997

Please enter the forms of contraception:

Primary: Abstinence

Barrier/Primary: None

Important Information

- I confirm that my patient understands that abstinence means that she ***will not have sex*** or sexual contact with any male 24 hours a day, 7 days a week. She has been informed to tell me immediately if she decides not to be abstinent.
- One of the most common reasons that women get pregnant is that they engage in sexual activity when they have planned to be abstinent.

Ok

Back | Continue | Cancel

Please click button only once.

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A secondary method will not be allowed to be entered if abstinence is selected as the primary method.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Did not fill Rx in previous window – Message

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3307071977
First Name: Male
Last Name: Patient
Date of Birth: 07/07/1977

More Information

iPLEDGE has no record of this patient filling a prescription in their previous prescription window. Did this patient fill their prescription during their previous prescription window?

- Yes
- No
- I do not know

Submit

Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number:	3304181997
First Name:	Female
Last Name:	Patient
Date of Birth:	04/18/1997

Important Information

Note - The confirmatory pregnancy test (just prior to the patient starting isotretinoin therapy) should be performed during the first 5 days of the patient's menstrual cycle.

Back | Continue | Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after closing of popup message)

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Notice!

You must be in receipt of the actual laboratory pregnancy test results before entering them into the iPLEDGE Program.

Intentionally entering a negative result in anticipation of receiving a negative laboratory result is Non-Compliance (see Non-Compliance Action Policy) and **may result in Permanent Deactivation from the iPLEDGE Program resulting in a permanent loss of isotretinoin prescribing privilege.**

Confirm

Prescriber Diagnosis: Pregnant Not Pregnant

Back Continue Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after confirming receipt of laboratory test)

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Confirm Patient Counseling

Confirm | Contraceptions | Pregnancy Result | Finish

Identification Number: 3304181997
First Name: Female
Last Name: Patient
Date of Birth: 04/18/1997

Pregnancy Test Specimen collected on: / /

Pregnancy Test Type:
- Quantitative Serum
- Qualitative Serum
- Urine

Lab Test Results: Positive Negative

Prescriber Diagnosis: Pregnant Not Pregnant

Back Continue Cancel

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Finish

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Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Confirm | Contraception | Pregnancy Test | Finish

Identification Number:	3304181997
First Name:	Female
Last Name:	Patient
Date of Birth:	04/18/1997

Confirm Patient Counseling is Complete.
The patient's Program Status is **Required to Demonstrate Comprehension**.
The patient must answer her Comprehension questions, and then may have her prescription filled before 11:59 PM Eastern Time on 6/7/2015.

Finish

Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button – Male - Confirm

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Confirm Patient Counseling

Confirm | Contraception | Pregnancy Result | Finish

Identification Number: 3304041914
First Name: Male
Last Name: Patient
Date of Birth: 04/04/1914

☐ I have counseled this patient on the following:

- Drug should not be shared with anyone
- Blood should not be donated while taking isotretinoin
- Patient program requirements

☐ Check this box if this is the patient's last month of treatment.

○ Yes ○ No In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.

Selecting the "Continue" button confirms that you have provided the monthly counseling to this patient.

Continue Cancel
Please click button only once.

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Prescriber - Manage Patients – Confirm Patient Counseling Button - Male - Finish

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Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Confirm | Contraception | Pregnancy Test | Finish

Identification Number:	3304041914
First Name:	Male
Last Name:	Patient
Date of Birth:	04/04/1914

Confirm Patient Counseling is Complete.
The patient's Program Status is **Qualified to Receive Drug**.
The patient may obtain their prescription at the pharmacy. The patient must obtain the prescription before 11:59 PM Eastern Time on 6/30/2015.

Finish

Please click button only once.

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Prescriber - Manage Patients – Edit Patient Contraception Button
Patient is in Window 1, or previous prescription window contraception selection is non-Abstinence.

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Change Contraception Choices

Identification Number: 3304181997
First Name: Female
Last Name: Patient
Date of Birth: 04/18/1997
Current Program Status: Required to Demonstrate Comprehension

Current contraception methods:
Primary: Birth Control Pills
Barrier/Primary: Male Latex Condom

Please enter patients new contraception methods:
** denotes required field*
Primary:* Birth Control Pills
Barrier/Primary:* Partner's Vasectomy

Cancel | Save Changes

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Prescriber - Manage Patients – Edit Patient Contraception Button
Patient's previous prescription window contraception selection is Abstinence.

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Change Contraception Choices

Identification Number: 7006021994
First Name: Ipledge
Last Name: Test2
Date of Birth: 06/02/1994
Current Program Status: Required to Demonstrate Comprehension

Current contraception methods:
Primary: Abstinence
Barrier/Primary: None

Please enter patients new contraception methods:
** denotes required field*
Primary:* Birth Control Pills
Barrier/Primary:* Male Latex Condom
☑ I understand that switching from Abstinence requires a 30 day waiting period.

Cancel Save Changes

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Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Specimen Collection Date

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Enter Post-therapy Pregnancy Test Results

Identification Number:	3011101991
First Name:	FCBP
Last Name:	Patient
Date of Birth:	11/10/1991
Current Program Status:	Permanently Lost to Follow Up

Enter the Specimen Collection Date: Jun / 1 / 2015

Continue Cancel

Please click button only once.

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Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Pregnancy Test Type

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Enter Post-therapy Pregnancy Test Results

Identification Number:	3011101991
First Name:	FCBP
Last Name:	Patient
Date of Birth:	11/10/1991
Current Program Status:	Post Therapy

Confirm the Specimen Collection Date:
Specimen Collection Date you entered is: **6/1/2015**

These results will be entered as an Initial Post Therapy Pregnancy Test. The 30 day post therapy pregnancy test must have a specimen collection date on or after 7/1/2015.

☑ Confirm the Specimen Collection Date.

Enter the Pregnancy Test Results

Pregnancy Test Type:
- (●) Quantitative Serum
  - Serum hCG: 2 mIU/ml
- ( ) Qualitative Serum
- ( ) Urine

Lab Test Results: ( ) Positive (●) Negative

Prescriber Diagnosis: ( ) Pregnant (●) Not Pregnant

Back | Continue | Cancel
Please click button only once.

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Prescriber - Manage Patients – Post-therapy Pregnancy Test Button - Enter Post-therapy Pregnancy Test Results - Finish

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Enter Post-therapy Pregnancy Test Results

These results have been successfully entered as an Initial Post Therapy Pregnancy Test. The 30 day post therapy pregnancy test is due with a specimen collection date on or after 7/1/2015.

Finish

Please click button only once.

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Prescriber - Manage Patients – Check Patient Status Button – FRP

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Patient Program Status as of 6/1/2015 2:44 PM Eastern Time

Name: Female Patient
Program Status: Required to Demonstrate Comprehension
Action: No prescriber action is required at this time.

Prescriptions Filled
None
Denial messages

Information: Before the patient can fill and pick up her prescription, she must demonstrate her iPLEDGE comprehension by answering questions in the system. This can be done anytime before the 7-day prescription window expires.

June 2015

Sun	Mon	Tue	Wed	Thu	Fri	Sat
31	1 First day patient may answer their questions More...	2 Patient may answer their questions More...	3 Patient may answer their questions More...	4 Patient may answer their questions More...	5 Patient may answer their questions More...	6 Patient may answer their questions More...
7 Last day patient may answer their questions More...	8 First day patient may have a pregnancy test More...	9	10	11	12	13

Key
- Today or future day for an active 7 day window
- A past day for a 7 day window
- A 7 day window that has expired without prescription fill
- Action may occur on this date or any date after

You may click on underlined text to perform the required action.

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Patient Program Status Screen – More Information

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Patient Program Status as of 4/21/2016 2:37 PM Eastern Time

Name: rayTest10 g
Program Status: Medically Impaired Requires Confirmation
Action: Confirm Patient

Prescriptions Filled
None
Denial messages

Information: The patient must have a pregnancy test and be counseled by you. You must confirm this counseling and enter the results of the pregnancy test in the iPLEDGE system. This can occur immediately.

More Information

This is the first day that the patient can have a pregnancy test performed before getting an isotretinoin prescription filled.

For a female of reproductive potential, medically impaired patient (MIP), there are two steps required for each prescription of isotretinoin.

The first step is for the patient to obtain a CLIA certified pregnancy test to ensure they are not pregnant.

The second step is counseling by the prescriber. The prescriber must confirm this counseling in the iPLEDGE system. The results of the pregnancy test will be entered in the system by the prescriber as part of the confirmation.

Confirmation, including entering the results of the pregnancy test and confirming patient counseling in the system by the prescriber creates the 7-day prescription window. The 7-day prescription window is the duration of time that the patient is allowed to obtain this prescription if they have successfully completed the two steps.

Once the prescriber has confirmed counseling in the system, the patient will be Qualified to Receive Drug. This means the patient may obtain their prescription at the pharmacy before 11:59 PM Eastern Time on the last day of the 7-day prescription window. The pharmacy is not allowed to fill or dispense the prescription after the window ends. The date of the pregnancy test as entered in the system by the prescriber becomes Day 1 of the 7-day prescription window.

The patient will need to start the two steps over, including another CLIA certified pregnancy test, if the prescription is not obtained during the 7-day prescription window.

The expiration date of the current 7-day prescription window can be found on the Patient Program Status page.

Once the prescriber has entered the pregnancy test results and has confirmed counseling in the iPLEDGE system, this calendar will show the 7-day prescription window.

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Prescriber - Manage Patients – Check Patient Status Button – FRP – Patient with expired Rx window

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Patient Program Status as of 6/1/2015 3:46 PM Eastern Time

Name: iPledge Test3
Program Status: Registered
Action: No prescriber action is required at this time.

Prescriptions Filled
None
Denial messages

Information: The patient's 7-day prescription window expired, and it was her first window of therapy. Since her first prescription must be preceded by two negative pregnancy tests at least 19 days apart, the patient must wait at least 12 days beyond the end of her missed 7-day prescription window before her next pregnancy test. This test must be in the first 5 days of her menstrual cycle.

May 2015

Sun	Mon	Tue	Wed	Thu	Fri	Sat
24	25 Patient may obtain their prescription More...	26 Patient may obtain their prescription More...	27 Patient may obtain their prescription More...	28 Patient may obtain their prescription More...	29 Patient may obtain their prescription More...	30 Patient may obtain their prescription More...
31 Patient may obtain their prescription More...	1 First day of required lockout More...	2	3	4	5	6
7	8	9	10	11	12	13 First day patient may have a pregnancy test More...
14	15	16	17	18	19	20

Key
- Today or future day for an active 7 day window
- A past day for a 7 day window
- A 7 day window that has expired without prescription fill
- Action may occur on this date or any date after

You may click on underlined text to perform the required action.

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Prescriber - Manage Patients – Check Patient Status Button – Male/FNRP

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Patient Program Status as of 6/1/2015 3:59 PM Eastern Time

Name: FNRP Patient
Program Status: Qualified to Receive Drug
Action: No prescriber action is required at this time.
Expire Date: 6/30/2015 11:59:59 PM

Prescriptions Filled
None
Denial messages

Information: The patient may fill and pick up their prescription at the pharmacy. The patient must obtain the prescription before 11:59 PM Eastern Time on the last day of the prescription window.

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Prescriber - Manage Patients – Re-Register Patient Button

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)
- Patient is Male

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – Patient linked to a different Prescriber

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Re-Register Patient

The patient you have selected to re-register is directly linked to iPLEDGE Prescriber, and you are a delegate of this prescriber. Do you wish to re-register this patient and become the primary prescriber, or re-register this patient and leave iPLEDGE Prescriber as the primary prescriber?

- Make me the primary prescriber
- Leave iPLEDGE Prescriber as primary prescriber

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- (●) Patient is a Female of Reproductive Potential (FRP)
- ( ) Patient is a Female NOT of Reproductive Potential (FNRP)
- ( ) Patient is Male

Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP – In-Office Pregnancy Test Results

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter In-Office Pregnancy Test Results:

** denotes required field*

In-Office Pregnancy Test Result:

- In-Office Pregnancy Test is Positive
- In-Office Pregnancy Test is Negative

Date of In-Office Positive or Negative Pregnancy Test (MM/DD/YYYY)*

Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP – Patient Information

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Re-Register Patient

Category | Review | Pregnancy Results | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information:

** denotes required field*

First Name* Jenna
Last Name* Jones
Middle Initial
Address* 421 Seabrook Road
City* Blue Bell
State* PA
ZIP* 19854

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP – Patient Information

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Jenna Jones - continued:

** denotes required field*

Phone Number*: 2155221212
Email: jennaj@yahoo.com
Date of Birth (MM/DD/YYYY)*: 3/7/2000
Last Four Digits of Social Security Number*: 7542
☐ Check this box if the patient doesn't have a social security number.
Preferred Method of Communication*: Email
☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP – Patient Information Review

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Jenna Jones
421 Seabrook Road
Blue Bell, PA 19854

Phone Number: 2155221212
Email: jennaj@yahoo.com

Preferred Method of Communication:
Email

Date of Birth: 3/7/2000
Last Four Digits of Social Security Number: 7542

I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FRP – Finish

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Unknowns | Finish

Patient Registration is complete for Jenna Jones.
Patient may use their current Patient ID and Password.

This patient has a 30 day wait period before she can be confirmed. This 30 day wait period begins on the date of registration. You may confirm this patient on or after 7/1/2015.

Do not give the patient a prescription to fill until after you provide this confirmation.

Finish

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- ○ Patient is a Female of Reproductive Potential (FRP)
- ◉ Patient is a Female NOT of Reproductive Potential (FNRP)
- ○ Patient is Male

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Determine Patient Category

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

You have indicated that this patient is a female. The questions that follow will assign a risk category to this female patient, based on her childbearing potential according to the requirements of the iPLEDGE Program.

All female patients are considered Female of Reproductive Potential (FRP) unless one or more of the following applies:

1. Patient has had a hysterectomy
2. Patient has had a bi-lateral oophorectomy
3. Patient is post-menopausal

Please note that the following conditions DO NOT qualify a patient to be moved from the FRP risk category.

- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please acknowledge your understanding of the qualification criteria as presented to proceed with assigning a risk category to this patient.

I Acknowledge | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Determine Patient Category – Question 1 of 3

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Has patient had a hysterectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Determine Patient Category – Question 2 of 3

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Has patient had a bi-lateral oophorectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Determine Patient Category – Question 3 of 3

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

For the iPLEDGE Program, a woman is considered post-menopausal upon cessation of previously occurring menses as a result of ovarian failure with documentation of hormonal deficiency by a certified healthcare provider. (i.e. spontaneous menopause)

Hormonal deficiency should be properly documented in the case of spontaneous menopause as follows:

1. If age > 54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed.

2. If age < 54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

Using the definition above, is this patient post-menopausal?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – System determines Patient Category as FRP

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female of Reproductive Potential (FRP)**

Based on the following criteria:

Is patient Male?	No
Has patient had a hysterectomy?	No
Has patient had a bi-lateral oophorectomy?	No
Is this patient post-menopausal?	No

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.
If your responses are correct, but you still believe this patient to be a Female of NON-Reproductive Potential, click Request FNRP Status.

Back | Continue | Request FNRP Status

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UBC
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Prescriber - Manage Patients – Re-Register Patient Button – Request FNRP Status

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Notice!
Your responses indicate that this patient should be registered as a Female of Reproductive Potential (FRP). However you are requesting to register this patient as a Female NOT of Reproductive Potential (FNRP). **This must be due to an unusual circumstance or unique medical condition not covered in the definition of FNRP for the iPLEDGE Program.**

The following are not reasons to register a patient as an FNRP, **and requests based on these reasons will be denied.**
- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please contact the Call Center at 1-866-495-0654 to provide further information. You may be required to provide documentation to support this request.

If this request is denied, the patient will need to be re-registered after a negative pregnancy test. Isotretinoin therapy can only begin 30 days from the date the patient is re-registered.

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Re-Register Patient

Category | Review | Pregnancy Results | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information:

** denotes required field*

First Name* Lorie
Last Name* Boswell
Middle Initial
Address* 1 Turnpike Way
Suite 1
City* Napa
State* MD
ZIP* 40517

Continue Cancel

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Lorie Boswell - continued:

** denotes required field*

Phone Number*: 8775552087
Email: steve.weitzman@UBC.com
Date of Birth (MM/DD/YYYY)*: 5/17/1971
Last Four Digits of Social Security Number*: 7505
☐ Check this box if the patient doesn't have a social security number.
Preferred Method of Communication*: U.S. Mail
☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Patient Information Review

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Lorie Boswell
1 Turnpike Way
Suite 1
Napa, MD 40517

Phone Number: 8775552087
Email: steve.weitzman@UBC.com

Preferred Method of Communication:
U.S. Mail

Date of Birth: 5/17/1971
Last Four Digits of Social Security Number: 7505

I have obtained the signed program consent form from the patient.

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Prescriber - Manage Patients – Re-Register Patient Button – Request FNRP Status – Finish

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Finish

Patient Lorie Boswell.
Patient may use their current Patient ID and Password.

Registration is not complete until this request for FNRP status is approved by iPLEDGE. This Patient will not be able to start therapy until approved as a FNRP, or until you register the patient as a FRP.

Please contact the Call Center at 1-866-495-0654 to provide further information. You may be required to provide documentation to support this request.

Select the Finish button below to complete this portion of the patient's registration.

Finish

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – System determines Patient Category as FNRP

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female NOT of Reproductive Potential (FNRP)**

Based on the following criteria:

Is patient Male?	No
Has patient had a hysterectomy?	**Yes**
Has patient had a bi-lateral oophorectomy?	**Yes**
Is this patient post-menopausal?	**Yes**

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

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Re-Register Patient

Category | Review | Pregnancy Results | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information:

** denotes required field*

First Name* Female
Last Name* Patient
Middle Initial
Address* 123 Test Drive
Suite 123
City* Test City
State* AL
ZIP* 11122

Continue Cancel

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Female Patient - continued:

** denotes required field*

Phone Number* 1231231231
Email

Date of Birth (MM/DD/YYYY)* 10/20/1970
Last Four Digits of Social Security Number* 2070

☐ Check this box if the patient doesn't have a social security number.

Preferred Method of Communication* U.S. Mail

☐ I have obtained the signed program consent form from the patient.

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Prescriber - Manage Patients – Re-Register Patient Button – FNRP – Patient Information Review

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Female Patient
123 Test Drive
Suite 123
Test City, AL 11122

Phone Number: 1231231231
Email: Not provided

Preferred Method of Communication:
U.S. Mail

Date of Birth: 10/20/1970
Last Four Digits of Social Security Number: 2070

I have obtained the signed program consent form from the patient.

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Unknowns | Finish

Patient Registration is complete for FNRP Patient.
A password will be mailed to the patient, and should be received within 5 to 10 days.

Before FNRP Patient can fill a prescription, you must confirm patient counseling in the system.
Please click the Continue button below to start the confirmation process.

Continue

Otherwise select the Finish button below to complete FNRP Patient's registration.
Note: you may confirm FNRP Patient at a later date using the Manage Patients screen.

Finish

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Prescriber - Manage Patients – Re-Register Patient Button – MALE

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)
- Patient is Male

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – MALE – Patient Information

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Re-Register Patient

Category | Review | Pregnancy Results | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information:

** denotes required field*

First Name* Male
Last Name* Patient
Middle Initial
Address* 123 Test
City* Testing
State* PW
ZIP* 12345

Continue Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – MALE – Patient Information

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Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Enter Patient Information for Male Patient - continued:

** denotes required field*

Phone Number* 1231231231
Email

Date of Birth (MM/DD/YYYY)* 8/28/1968
Last Four Digits of Social Security Number* 1968

☐ Check this box if the patient doesn't have a social security number.

Preferred Method of Communication* U.S. Mail

☐ I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Prescriber - Manage Patients – Re-Register Patient Button – MALE – Patient Information Review

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Patient Information Review:

Male Patient
123 Test
Testing, PW 12345

Phone Number: 1231231231
Email: Not provided

Preferred Method of Communication:
U.S. Mail

Date of Birth: 8/28/1968
Last Four Digits of Social Security Number: 1968

I have obtained the signed program consent form from the patient.

Back | Continue | Cancel

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Re-Register Patient

Category | Review | Pregnancy Result | Patient Info | Uncovered | Finish

Patient Registration is complete for Male Patient.
Patient may use their current Patient ID and Password.

Before Male Patient can fill a prescription, you must confirm patient counseling in the system. Please click the Continue button below to start the confirmation process.

Continue

Otherwise select the Finish button below to complete Male Patient's registration.
Note: you may confirm Male Patient at a later date using the Manage Patients screen.

Finish

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Prescriber - Manage Patients – Change Patient Type Button – Change to FRP

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

Select Patient Category.

- (●) Patient is a Female of Reproductive Potential (FRP)
- ( ) Patient is a Female NOT of Reproductive Potential (FNRP)

Continue Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Enter In-Office Pregnancy Test Results:
** denotes required field*

In-Office Pregnancy Test Result:

- (●) No Pregnancy Test Result
- ( ) In-Office Pregnancy Test is Positive
- ( ) In-Office Pregnancy Test is Negative

Date of Positive or Negative In-Office Pregnancy Test (MM/DD/YYYY)*

Continue | Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results – Finish

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Patient iPLEDGE Patient.
Patient Type has been changed to: Female of Reproductive Potential (FRP)
Program Status has been changed to: Registered

Patient may use their current Patient ID and Password.

Patient must be given a pregnancy test before beginning a new course of treatment. After a pregnancy test has been administered, return to the Manage Patients screen and select the Complete Change Patient Type button to enter the pregnancy test results. The date the pregnancy test is entered will be the date of registration for the new course of treatment.

Patient must wait at least 30 days after the date of registration before she can start the process for the first prescription. The patient's next pregnancy test after the 30 day wait is over should be done during the first 5 days of her menstrual period.

Remind this patient to use two forms of contraception.

Finish

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Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – Negative Pregnancy Test Results

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Enter In-Office Pregnancy Test Results:
** denotes required field*

In-Office Pregnancy Test Result:

- No Pregnancy Test Result
- In-Office Pregnancy Test is Positive
- In-Office Pregnancy Test is Negative

Date of Positive or Negative In-Office Pregnancy Test (MM/DD/YYYY)*

Continue | Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – Negative PT Results – Finish

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Patient iPLEDGE Patient.
Patient Type has been changed to: Female of Reproductive Potential (FRP)
Program Status has been changed to: Registered

Patient may use their current Patient ID and Password.

A new course of treatment has been initiated. This patient has a 30 day wait period before she can be confirmed. You may confirm this patient on or after 7/1/2015.

A second pregnancy test is required when the patient is confirmed.

For patients with regular menstrual cycles, the second pregnancy test should be done during the first 5 days of the menstrual period immediately preceding the beginning of isotretinoin therapy, and after the patient has used 2 forms of contraception for 1 month.

For patients with amenorrhea, irregular cycles, or using a contraceptive method that precludes withdrawal bleeding, the second pregnancy test must be done immediately preceding the beginning of isotretinoin therapy and after the patient has used 2 forms of contraception for 1 month.

Finish

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

Select Patient Category.

- ○ Patient is a Female of Reproductive Potential (FRP)
- ◉ Patient is a Female NOT of Reproductive Potential (FNRP)

Continue Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

You have indicated that this patient is a female. The questions that follow will assign a risk category to this female patient, based on her childbearing potential according to the requirements of the iPLEDGE Program.

All female patients are considered Female of Reproductive Potential (FRP) unless one or more of the following applies:

1. Patient has had a hysterectomy
2. Patient has had a bi-lateral oophorectomy
3. Patient is post-menopausal

Please note that the following conditions DO NOT qualify a patient to be moved from the FRP risk category.

- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please acknowledge your understanding of the qualification criteria as presented to proceed with assigning a risk category to this patient.

I Acknowledge | Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Question 1 of 3

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

Has patient had a hysterectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

Has patient had a bi-lateral oophorectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Determine Patient Category:

For the iPLEDGE Program, a woman is considered post-menopausal upon cessation of previously occurring menses as a result of ovarian failure with documentation of hormonal deficiency by a certified healthcare provider. (i.e. spontaneous menopause)

Hormonal deficiency should be properly documented in the case of spontaneous menopause as follows:

1. If age > 54 years and with the absence of normal menses: Serum FSH (Follicle Stimulating Hormone) level elevated to within the post-menopausal range based on the laboratory reference range where the hormonal assay is performed.

2. If age < 54 years and with the absence of normal menses: Negative serum or urine -HCG with concurrently elevated serum FSH (Follicle Stimulating Hormone) level in the post-menopausal range, depressed estradiol (E2) level in the post-menopausal range, and absent serum progesterone level, based on the laboratory reference ranges where the hormonal assays are performed.

Using the definition above, is this patient post-menopausal?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

Continue | Cancel

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Review

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female of Reproductive Potential (FRP)**

Based on the following criteria:

Has patient had a hysterectomy?	No
Has patient had a bi-lateral oophorectomy?	No
Is this patient post-menopausal?	No

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.
If your responses are correct, but you still believe this patient to be a Female of NON-Reproductive Potential, click Request FNRP Status.

Back | Continue | Request FNRP Status

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Review Patient Category:

Based on your responses the iPLEDGE system has categorized this patient as follows:
Patient is a **Female of NON-Reproductive Potential (FNRP)**

Based on the following criteria:

Is patient Male?	No
Has patient had a hysterectomy?	**Yes**
Has patient had a bi-lateral oophorectomy?	**Yes**
Is this patient post-menopausal?	**Yes**

To confirm the patient category and proceed, click Continue.
To change your responses, click Back.

Notice!

Make sure that you are correctly classifying your patient as a Female of Non-Reproductive Potential (FNRP). Intentional falsification of patient classification type will result in **permanent deactivation from the iPLEDGE Program, and permanent loss of isotretinoin prescribing privileges.**

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Request FNRP

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Review Patient Category:

Notice!
Your responses indicate that this patient should be registered as a Female of Reproductive Potential (FRP). However you are requesting to register this patient as a Female NOT of Reproductive Potential (FNRP). **This must be due to an unusual circumstance or unique medical condition not covered in the definition of FNRP for the iPLEDGE Program.**

The following **are not** reasons to register a patient as an FNRP, **and requests based on these reasons will be denied.**
- Tubal Sterilization
- Partner Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopausal)

Please contact the Call Center at 1-866-495-0654 to provide further information. You may be required to provide documentation to support this request.

If this request is denied, the patient will need to be re-registered after a negative pregnancy test. Isotretinoin therapy can only begin 30 days from the date the patient is re-registered.

Back | Continue

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Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Request FNRP – Finish

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Change Patient Type

Category | Review | Pregnancy Result | Finish

Patient Joanne Purdy
Patient may use their current Patient ID and Password.

Registration is not complete until this request for FNRP status is approved by iPLEDGE. This patient will not be able to start therapy until approved as a FNRP, or until you register the patient as a FRP.

Please contact the Call Center at 1-866-495-0654 to provide further information. You may be required to provide documentation to support this request.

Select the Finish button below to complete this portion of the patient's registration.

Finish

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Prescriber - Manage Patients – Discontinue Patient Button – Discontinue Reasons

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Discontinue Patient

*denotes required field

Patient ID: 3911101993
First Name: FCBP
Last Name: Patient
Date of Birth: 11/10/1993

The iPLEDGE system has no record of a prescription being filled for this patient. Do you believe this patient has taken isotretinoin during this course of therapy?*

No Yes Not Sure

Discontinue Reason:*

Last Dosage Date:*

Patient Completed Therapy
Patient is Lost to Follow Up
Pregnancy
Patient has Insurance Considerations
Patient Never Started Therapy
Other

date of last dosage.

Cancel Continue

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Prescriber - Manage Patients – Report Pregnancy Button

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Report Pregnancy

Identification Number:	3304181997
First Name:	FCBP
Last Name:	Patient
Date of Birth:	04/18/1997
Current Program Status:	Registered

Enter the Specimen Collection Date: May / 28 / 2015

Continue Cancel

Please click button only once.

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Prescriber - Manage Patients – Report Pregnancy Button

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Report Pregnancy

Identification Number:	3304181997
First Name:	FCBP
Last Name:	Patient
Date of Birth:	04/18/1997
Current Program Status:	Registered

Confirm the Specimen Collection Date:
Specimen Collection Date you entered is: **5/28/2015**

☑ Confirm the Specimen Collection Date.

Pregnancy Test Type: ○ Quantitative Serum ◉ Qualitative Serum ○ Urine

Lab Test Results: ◉ Positive ○ Negative

Prescriber Diagnosis: ◉ Pregnant ○ Not Pregnant

You are reporting this patient pregnant.
To enter this patient's monthly pregnancy results, please use the Confirm Patient Counseling feature found on the Manage Patients screen.

Back | Report Patient Pregnant
Please click button only once.

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Prescriber - Manage Patients – Report Pregnancy Button – Confirmation

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Report Pregnancy

Identification Number:	3911101993
First Name:	FCBP
Last Name:	Patient
Date of Birth:	11/10/1993
Current Program Status:	Registered

- Based on your response, the status of this patient will be indicated as pregnant. Please confirm that this is the correct patient for this diagnosis.

Go Back | Confirm

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Prescriber Information

About Prescriber Information
The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. The resources below present the program requirements and help you prepare and plan treatments with patients during the course of isotretinoin therapy.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.
To order Educational Materials, please click here.

Patient Information:
- Mylan Amnesteem Medication Guide
- Teva Claravis Medication Guide
- Ranbaxy Sotret Medication Guide
- VersaPharm Myorisan Medication Guide
- Ranbaxy Absorica Medication Guide
- Dr. Reddy's Zenatane Medication Guide
- The iPLEDGE Program Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- The iPLEDGE Program Guide to Isotretinoin For Male Patients and Female Patients Who Cannot Get Pregnant
- The iPLEDGE Program Birth Control Workbook (for patients)
- The iPLEDGE Program Contraception Referral Form and Contraception Counseling Guide
- Isotretinoin Contraception Referral Form
- Patient Flowchart

Prescriber Information:
- The iPLEDGE Program Patient Introductory Brochure
- The Guide to Best Practices for the iPLEDGE Program
- The iPLEDGE Program Prescriber Contraception Counseling Guide
- Prescriber Checklist for Female Patients of Reproductive Potential
- Prescriber Checklist for Male Patients and Female Patients Who Cannot Get Pregnant
- Recognizing Psychiatric Disorders in Adolescents and Young Adults A Guide for Prescribers of Isotretinoin
- Teva Claravis Package Insert
- Mylan Amnesteem Package Insert
- Ranbaxy Sotret Package Insert
- VersaPharm Myorisan Package Insert
- Ranbaxy Absorica Package Insert
- Dr. Reddy's Zenatane Package Insert
- Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)
- Patient Information/Informed Consent (for all patients)
- Prescriber Activation Instructions
- Prescriber Flowchart
- Instructions for Registering and Managing Office Staff Designees
- Lessons Learned About Leftover Medication
- Lessons Learned About Birth Control

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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Prescriber - Order Materials

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Order Materials

Enter quantities you would like to order

0 Checklists for Female Patients of Reproductive Potential *(1 to 3 pads of 50 tear sheets)*

0 Checklists for Male and Female Patients Not of Reproductive Potential *(1 to 3 pads of 50 tear sheets)*

0 DVD containing the videos "Be Prepared, Be Protected" and "Be Aware: The Risk of Pregnancy While on Isotretinoin" *(1 DVD)*

0 Patient Introductory Brochure *(1 to 3 packages of 5)*

0 Patient Educational Kit for Female Patients of Reproductive Potential *(1 to 10 kits)*

0 Patient Educational Kit for Males and Females Not of Reproductive Potential *(1 to 10 kits)*

0 Prescriber Educational Kit *(1 Kit)*

0 Spanish Patient Introductory Brochure *(1 to 3 packages of 3)*

0 Spanish Patient Educational Kit for Female Patients of Reproductive Potential *(1 to 10 kits)*

0 Spanish Patient Educational Kit for Males and Females Not of Reproductive Potential *(1 to 10 kits)*

Place Order

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Update My Information

Change Password

Change Date of Personal Significance

Edit Prescriber Demographics

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Prescriber - Update My Information – Change Password

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Change Password

** denotes required field*

Old Password *
New Password *
Confirm New Password *

Save Changes

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Prescriber - Update My Information – Change DOPS

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Change Date of Personal Significance

Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the Call Center.

** denotes required field*

Password: *

Date of Personal Significance: (MM/DD/YYYY) / / *

Confirm Date of Personal Significance: (MM/DD/YYYY) / / *

Save Changes

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Prescriber - Update My Information – Contact Info

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Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center.

** denotes required field*

First Name*	Last Name*	Middle Initial	Suffix	Specialty
iPLEDGE	Prescriber		MD	Derm

Address*
123 Test Drive
Suite 200

City*	State*	Zip*
Test City	KS	12345

Phone Number *	Fax Number	Email *
555-555-1212		marcio.spieker@ubc.com

Preferred method of communication *
U.S. Mail

Cancel | Save Changes

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Accept Patient

Please enter the Patient Identification Number of the patient transferring into your care, and click the Look Up button.

Patient Identification Number

Look Up

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Manage Delegates and Designees

Delegates

A prescriber can delegate another registered and activated iPLEDGE prescriber to cover for him/her during a scheduled absence (travel, vacation, etc.). This also can be used to delegate to another registered and activated prescriber in a multiple doctor practice where a patient may see any of the doctors in the office. Delegate status has an expiration date that can be set by the delegating prescriber.

Manage Delegates

Designees

A designee is a staff member in the prescriber's office. A registered designee may perform all patient functions on behalf of the prescriber. An office designee may support all the registered prescribers in a multi-physician practice and will also have rights for any patient of a delegate prescriber. Each office staff designee will only need to register once, even if they support several prescribers. Also, if a prescriber is not activated in the iPLEDGE system, neither the prescriber nor the designated office staff can register a patient. The prescriber is responsible for any actions of all designees under him/her.

Register New Designee

Manage Designees

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Manage Delegates

Delegates are prescribers that are registered and activated in the iPLEDGE Program that you allow to manage your patients.

- To add a delegate, enter the delegate's prescriber username, optionally using the expiration date to make the delegate temporary, then click the Add button.
- To remove a delegate, select the delegate from the list below and click the Remove button.
- To update a delegate, select the delegate from the list below, make your changes, then click the Update button.

Your current delegates

iPledge Delegate until 02/20/2015

** denotes required field*

Delegate Prescriber Username*

Expiration Date (MM/DD/YYYY) (ie. temporary delegate)

Add Remove Update

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Prescriber - Register New Designee

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Register New Designee

Designees are office staff that are registered in the iPLEDGE Program. To register the designee, enter the designee information and click the Save and Print button.

The registered prescriber is responsible for all information entered, and activities performed, in the iPLEDGE Program by the office staff designee.

** denotes required field*

First Name* Last Name* MI

Address *

City* State* Zip*

Phone* Fax

Email

Preferred method of communication*

Save and print designee's registration

To complete your designee's registration, click the Save and Print button below, have the designee sign the form, then mail or fax the signed form to the address or fax number on the form.

Save and Print

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Prescriber - Manage Designees

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Manage Designees

Designees are office staff that are registered in the iPLEDGE Program that you allow to manage your patients.

The registered prescriber is responsible for all information entered, and activities performed, in the iPLEDGE Program by the office staff designee.

Your designees

iPledge Designee
Designee iPledge
iPledge Designee
SARAH Borkowsky

** denotes required field*

Designee Username*

Add Remove

- To add a designee, enter the designee's username then click the Add button.
- To remove a designee, select the designee from the list above and click the Remove button.

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Prescriber - Register Designee

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The registered prescriber is responsible for all information entered, and activities performed, in the iPLEDGE program by the office staff designee.

** denotes required field*

First Name* Last Name* MI

Address *

City* State* Zip*

Phone* Fax

Email

Preferred method of communication*

Save and print designee's registration

To complete your designee's registration, click the Save and Print button below, have the designee sign the form, then mail or fax the signed form to the address or fax number on the form.

Save and Print

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Prescriber - Program Status

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Prescriber Program Status

Your Program Status: Attested
Program status expiration date: 5/28/2016

Patients

Full Name	Phone	Date of Birth	Type	Status
FCBP, FEMALE	123-123-1231	10/20/1970	Patient FRP	Inactive
gdtest, Test2	222-222-2222	08/29/1969	Patient FRP	Inactive
Jones, Jenna	215-522-1212	03/07/2000	Patient FRP	Inactive
kyesy1, ktest1	999-999-9999	01/01/1940	Patient FRP	Permanently Lost to Follow Up
Patient, Male	123-123-1231	08/28/1968	Patient FNRP	Inactive
PaTient, FCBP	123-121-2311	10/21/1921	Patient FRP	Permanently Lost to Follow Up
Patient, FCBP	555-555-1212	11/10/1991	Patient FRP	Permanently Lost to Follow Up
Patient, FCBP	555-555-1212	11/10/1993	Patient FRP	Permanently Lost to Follow Up

1 2 3 4

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Prescriber - Find a Participating Pharmacy

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Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button

Zip | City | State

Search

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iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PRESCRIBER
C. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- How can I login using my telephone?

  To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system will ask you to indicate which type of user you are (prescriber, patient, pharmacy or designee) and then prompt you to enter your user ID followed by the # button. You may be presented with additional prompts to confirm your user id.

  For each character of your username, press the key on the touch pad that corresponds to the number or letter. For example, the 2 button on the phone is used to enter either the number 2 or the letters A, B and C. The # must be pressed after all characters have been entered.

  For example, if your username is 12345, type 12345# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 2512345#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.

B. PATIENT
C. PHARMACY
D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.
- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

D. PRESCRIBER

- Please explain the registration process.
- We received new educational materials, when should we start to use them?
- How are iPLEDGE patient numbers assigned?

  Once a Prescriber performs the "Activation" step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber's address via UPS. The shipment includes two yellow kits (booklets) for females of reproductive potential and two green kits (booklets) for male patients or female patients who cannot get pregnant. Inside each kit you will find perforated, tear-off patient ID cards. Duplicates are provided in case the patient loses his or her ID card. The prescriber should separate off one card and give it to the patient along with the kit that contains the remaining duplicate ID cards. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. The prescriber should peel off the small tab that lists the patient's ID number, which is located on the same page containing the tear-off cards, and affix it in the patient's chart. For each new patient you must have a new patient educational kit available to provide to the patient.
- I either lost or forgot my password. How do I reset my password?
- Do I need to activate my registration annually?

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Frequently Asked Questions (FAQ)

- I either lost or forgot my password. How do I reset my password?
- Do I need to activate my registration annually?
- What are the steps to re-activate my registration?
- Can prescribers edit their own (demographic) information?
- What is the difference between a Delegate and a Designee?
- How does an Office Staff Designee register and become affiliated to a Prescriber?

  Registration and affiliation is a two-step process.

  Registration - To register an Office Staff Designee, the **Prescriber** must login to the iPLEDGE website and click on "Manage Delegates/Designees" and then select "Register New Designee". The **Prescriber** must then complete the fields on the registration form, click on "Save and Print" at the bottom of the page, and sign the printout. The signed form must then be faxed to the number that appears on the form. Upon processing of the signed form, the Designee's Username and Password is sent via US Mail. Each designee should be registered only ONCE in the iPLEDGE system no matter how many prescribers he or she supports.

  Affiliation - Upon receipt of the Username and Password, the Designee may need to arrange with the Prescriber to affiliate the Designee to the Prescriber. To do this the Prescriber must login to the iPLEDGE website and click on "Manage Delegates/Designees" and then select "Manage Designees". The Prescriber must then enter the Designee's username into the Designee Username box and click on the "Add" button. The Designee's name will then appear on the "Your Designees" list and the Designee may begin to perform functions on behalf of the Prescriber. If the office does not have access to the iPLEDGE website, the prescriber can call 1-866-495-0654 (press 1, #0, 1, 4), to be assisted with Designee registration.

- How do I re-confirm a Patient of any type after their prescription window expires?
- Can Prescribers and Designees edit patient information?

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- How do I re-confirm a Patient of any type after their prescription window expires?
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- Please show the iPLEDGE Program requirements.
- Why is the "Confirm Counseling" button not available for my patient on the web?
- How does a patient become Lost to Follow Up?
- What should I do with patients with a Lost to Follow Up status?
- Why do I need to discontinue a patient?
- When should I discontinue a patient?
- What are the steps to discontinue a Patient?
- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE Program?

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Frequently Asked Questions (FAQ)

- How do I re-confirm a Patient of any type after their prescription window expires?

Prescribers must provide a new prescription and complete the qualification process again to ensure that all qualification criteria have been met and confirmed in the iPLEDGE system. System instructions are detailed below.

Females of Non-Reproductive Potential (FNRP) and MALES	Females of Reproductive Potential (FRP)
• To re-confirm a patient after their 30-day prescription window has expired, please do the following: - Go to the Manage Patient screen - Select the patient in the Manage Patient screen - Select the Confirm Patient Counseling button • The qualification process can start immediately after a patient's 30-day prescription window has expired or after a patient has successfully filled a prescription. • A new prescription must be provided to the patient	• To re-confirm an FRP after her 7-day prescription window has expired, please do the following: - Have the patient take a new pregnancy test - Go to the Manage Patient screen - Select the patient in the Manage Patient screen - Select the Confirm Patient Counseling button, enter the specimen collection date and the pregnancy test results. • A new prescription must be provided to the patient. **Note: If the Confirm Patient Counseling is grayed out, it means the patient is still within her 7-day prescription**

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Frequently Asked Questions (FAQ)

- Can Prescribers and Designees edit patient information?
- Please show the iPLEDGE Program requirements.

Females of Reproductive Potential (FRP)

Initial 30 Days

Day 1 = Patient Registration and entry of screening pregnancy results into the iPLEDGE system. Screening pregnancy test can occur up to 30 days prior to patient registration. Screening pregnancy test may be conducted in the prescriber's office.

30 Days - Patient must be on two forms of contraception for 30 days after patient registration. The patient must wait at least 30 days after registration to receive the first prescription.

First Month

- As early as Day 31 = Once the patient's 30 day waiting period has ended, the patient is eligible for the office visit. A pregnancy test must occur during the first 5 days of the patient's menstrual cycle. This, and all subsequent monthly pregnancy tests, must be conducted at a CLIA certified laboratory.

Days 1 to 7 of the 7-day prescription window

- The prescriber must confirm counseling, enter the date of the pregnancy specimen collection and the pregnancy test results. **The pregnancy test specimen collection date starts the 7-day prescription window.**
- The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements. **Note: The patient cannot perform this function until the pregnancy test specimen collection date and test results have been entered into the system by the prescriber/designee.**

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Frequently Asked Questions (FAQ)

- Discontinue the patient that has completed therapy. See "Why do I need to discontinue a patient?"
- The patient should not donate blood until she has been off isotretinoin therapy for at least 30 days.

Females of Non-Reproductive Potential (FNRP) and Males

Initial 30 Days

Day 1 = Patient Registration, eligible for the office visit and the prescriber has the ability to confirm counseling. There is no 30-day waiting period requirement.

Day 1

- The Confirmation Counseling Date. This date starts the 30-day prescription window.

Days 1 to 30

- The patient can fill and pick up the prescription.

Day 31

- The patient's 30-day prescription window is closed. There is no waiting period. The patient can re-qualify and have a new prescription filled immediately after the 30-day prescription window has expired or after successfully filling a prescription. A new prescription is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.

Each Subsequent Month (Through End of Therapy)

Day 1

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Frequently Asked Questions (FAQ)

- Please show the iPLEDGE Program requirements.
- Why is the "Confirm Counseling" button not available for my patient on the web?

There are several reasons why the "Confirm Counseling" button is not available for a patient.

1. The patient is a Female of Reproductive Potential (FRP) and was registered in the last 30 days. See "Please show the iPLEDGE Program requirements".
2. The patient is a Female of Reproductive Potential (FRP) who missed the prescription window for her first prescription and must wait at least 19 days between pregnancy tests to start the qualification process for another prescription.
3. a) For females of reproductive potential, the patient is still in her prescription window.
   b) For females of non-reproductive potential and male patients, the patient is still in his/her 30-day prescription window, and has not yet filled a prescription.
4. The patient's program status is one of the following:
   a. Lost To Follow Up
   b. Confirmed Positive
   c. Reported Positive
   d. Inactive

If your patient is not eligible for the next prescription according to the program timelines, the "Confirm Counseling" activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapse, a new prescription window can be started (for example, the previous prescription window has expired) and the system will allow you to restart the qualification process.

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- How do I re-confirm a Patient of any type after their prescription window expires?
- Can Prescribers and Designees edit patient information?
- Please show the iPLEDGE Program requirements.
- Why is the "Confirm Counseling" button not available for my patient on the web?
- How does a patient become Lost to Follow Up?

  Patients become lost to follow up due to the following conditions:

  - Patient has been in a "Registered" status for greater than 90 days and the prescriber/designee has not interacted with the patient's record
  - Patient has been in a "Requires Confirmation" status for greater than 53 days and the prescriber/designee has not interacted with the patient's record
  - FRPs who are missing their pregnancy test at date of last dose
  - FRPs who are missing their final pregnancy test 30 days post treatment
- What should I do with patients with a Lost to Follow Up status?
- Why do I need to discontinue a patient?

  It is critical to discontinue the patient to accurately reflect the patient's iPLEDGE status. It is also critical to obtain the post-discontinuation pregnancy tests per the program requirements (pregnancy test at date of last dose and pregnancy test 30 days post treatment). Discontinuing the patients (additionally for FRPs, documenting the necessary post treatment pregnancy tests) will avert phone calls from the iPLEDGE Program to your office inquiring about the patient's status.
- When should I discontinue a patient?
- What are the steps to discontinue a Patient?
- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?

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Frequently Asked Questions (FAQ)

- Why do I need to discontinue a patient?
- When should I discontinue a patient?

  Patients should be discontinued when the following occurs:

  - Patient completes treatment and is no longer taking the medication
  - Patient was never confirmed and did not receive a prescription from your office
  - Patient rescinded consent to participate

  Please note that when a FRP is discontinued, they must have a pregnancy test at date of last dose and a pregnancy test 30 days post treatment.

  Please see "What are the steps to discontinue a Patient?"
- What are the steps to discontinue a Patient?
- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?

  To resume a patient's active status, you need to speak with an iPLEDGE representative for technical support. Call 1-866-495-0654 (press 1, #0, 1, 2) to begin this process. You should not make any changes in the system with this patient until instructed to do so by the technical support agent. When calling, please have all pregnancy test results available for Females of Reproductive Potential (FRP).
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.
- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start

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Prescriber – FAQs/How To's

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Committed to Pregnancy Prevention

Welcome iPLEDGE Prescriber
Logout
Have Questions? Call our toll-free number 1-866-495-0654
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY

- HOME
- PRESCRIBER ACTIVATION
- REGISTER NEW PATIENT
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
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- Order Materials
- Update My Information
- Accept Patient
- Manage Delegates/Designees
- My Program Status
- Find a Participating Pharmacy
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Frequently Asked Questions (FAQ)

- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE Program?

  No, once the male patient or female of non-reproductive potential patient is registered, the prescriber can start the 30-day prescription window by going to the "manage patients" screen and confirming patient counseling. Male patients and females of non-reproductive potential do not have to answer questions each month in the iPLEDGE system; only females of reproductive potential need to do so. Males and females of non-reproductive potential do not need to use contraception to qualify for the iPLEDGE Program.

- Can pregnancy tests be conducted prior to the prescriber office visit?

  Yes, the pregnancy test can be done prior to the prescriber office visit. For females of reproductive potential, the initial screening pregnancy test (1st test) must be conducted on the date of registration or no more than 30 days prior to patient registration. For ongoing monthly pregnancy tests, the specimen must be collected and processed in a CLIA certified laboratory and the date of the specimen collection and the pregnancy test results must be entered to start the patient's 7-day prescription window.

  (See Package Insert for timing requirements). The date of the specimen collection for the pregnancy test is Day 1 of the 7-day prescription window for females of reproductive potential.

- Does a female of non-reproductive potential need to take pregnancy tests?

  No, only females of reproductive potential need to take pregnancy tests and answer monthly questions.

- How long does the patient need to wait between monthly pregnancy tests?

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Frequently Asked Questions (FAQ)

- Does a Female of Reproductive potential need to be on birth control or another form of contraception if she chooses abstinence? Or, is abstinence an acceptable option for iPLEDGE?

  The program requirement for an FRP is to be on two effective forms of birth control unless the patient chooses to be abstinent. A patient choosing abstinence does not need to choose another form of birth control. The system will default the secondary choice of "none" if abstinence is listed as the primary form. However, a secondary choice can still be entered.

  Abstinence means an FRP will not have sex or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do especially if the patient is used to having sex. It is easier not to have sex when it is a lifestyle choice, such as a religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence). If the patient cannot commit completely to not having sex while taking isotretinoin, she must use 2 separate, effective forms of birth control at the same time. The only exceptions are if she has had surgery to remove her uterus (a hysterectomy) or both of her ovaries (bilateral oophorectomy), or if her doctor has medically confirmed that she is post-menopausal.

- What are acceptable primary forms of birth control?

  Females of Reproductive Potential (FRP) must use two forms of effective birth control together correctly all the time (of which one must be a Primary form):

  - For at least one month before starting isotretinoin
  - While taking isotretinoin - treatment usually lasts four to five months
  - For one month after the last dose of isotretinoin - for continued protection against pregnancy

  Effective forms of contraception include both primary and secondary forms of

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ovaries (bilateral oophorectomy), or if her doctor has medically confirmed that she is post-menopausal.

- What are acceptable primary forms of birth control?
- What forms of birth control are NOT acceptable for the iPLEDGE Program?

  You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

  - Birth control pills without estrogen (progesterone-only mini-pills)
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
- What if the primary forms of contraception are contraindicated for the patient?
- Please explain the data entry requirements for contraception.
- What happens if Females of Reproductive Potential (FRP) patients answer their comprehension questions incorrectly?

  If an FRP answers her questions incorrectly, she will be given an opportunity to answer another question on the same topic. If she gets this wrong, she will be directed to review the appropriate educational materials. She can, at a later time, login again and attempt to answer the questions correctly.
- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?
- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?

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Frequently Asked Questions (FAQ)

- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?

  Patients can start a new prescription window as soon as the previous prescription window has expired. This would be 7 days for females of reproductive potential (with the exception of females of reproductive potential who miss their first prescription window and must wait at least 19 days between pregnancy tests) and either 30 days or the day after a prescription is filled for females of non-reproductive potential and male patients. All program requirements must be repeated to start the new prescription window. Prescriptions are limited to a maximum 30-day supply.

- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?

  Yes. The 30-day waiting period is required of all FRPs taking isotretinoin. There are no exceptions.

- How do I enter the pregnancy test results using Serum test versus urine tests?
- May I fax or phone in prescriptions to the pharmacy?
- How do I manage low-dose maintenance therapy for patients?

  All patients receiving isotretinoin, regardless of the dose prescribed, are required to have monthly office visits and new prescriptions written. No refills are permitted. For FRPs, monthly pregnancy tests must be conducted throughout treatment regardless of dose or duration. There are no exceptions. All patients receiving isotretinoin therapy must adhere to the requirements of the iPLEDGE program.

- Who needs to answer patient monthly comprehension questions?
- Can I download consent forms from www.ipledgeprogram.com?
- How can I order additional program materials?

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- What forms of birth control are NOT acceptable for the iPLEDGE Program?
- What if the primary forms of contraception are contraindicated for the patient?
- Please explain the data entry requirements for contraception.
- What happens if Females of Reproductive Potential (FRP) patients answer their comprehension questions incorrectly?
- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?
- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?
- How do I enter the pregnancy test results using Serum test versus urine tests?
- May I fax or phone in prescriptions to the pharmacy?
- How do I manage low-dose maintenance therapy for patients?
- Who needs to answer patient monthly comprehension questions?

  Females of reproductive potential must answer education questions to demonstrate their comprehension on a monthly basis by logging into the system (either by calling the automated telephone system at 1-866-495-0654 or accessing the website at http://www.ipledgeprogram.com/). Males and females of non-reproductive potential (FNRP) do not need to answer the monthly comprehension questions

- Can I download consent forms from www.ipledgeprogram.com?
- How can I order additional program materials?
- What if my office is excluded from HIPAA requirements?

E. ALL USERS

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Frequently Asked Questions (FAQ)

E. ALL USERS

- Does the iPLEDGE Program have a Privacy Statement?

  Yes. Everyone who wants to take the prescription medication isotretinoin is required to register and participate in the iPLEDGE Program. In order to help you fulfill the requirements of the program, iPLEDGE must obtain personal information from you. Protecting your privacy is very important to us. The complete iPLEDGE Privacy Statement can be found at the bottom of home page at http://www.ipledgeprogram.com/ by choosing the "Privacy Statement" feature.

- What happens if a patient loses his or her iPLEDGE ID card?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?
- At what date and time does my prescription window close?
- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?
- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- At what date and time does my prescription window close?

  Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may pick up your prescription. Patients will be provided with a message that states the ending date and time to pick up their prescription. This message has been updated to give patients the exact date and time when their window will close. For example, the message will read:

  "You may pick up your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

  Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to fill and pick up their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.

- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?

  Users can download the iPLEDGE materials from the website using Acrobat. The link to this free Acrobat download is available on any page that has materials available for download. The website has been updated to include additional documents for download and self-printing.

- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

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Based on the iPLEDGE Program requirements, listed below are actions that are required. Please provide the required information to ensure completion of all iPLEDGE Program requirements.

Name	Message	
Brown, Cindy 3301022009	Enter the initial post-therapy Pregnancy Test Results, due upon completion of therapy.	Take Action
Brown, Sandy 3301032009	One or both post-therapy Pregnancy Test Results due upon completion of therapy, (at completion and 30 days after completion of therapy) have not been entered into iPLEDGE. The Patient program status will change to Permanently Lost to Follow Up on 01/07/2010 if post-therapy Pregnancy Test Results are not entered.	Take Action
Dough , Jane 3304041964	Patient has been in "Registered" status for over 60 days. If no activity occurs, the system will discontinue this patient on 01/03/2010.	Take Action
Patienbt, Test 3311101910	During registration, this patient was determined to be a female of reproductive potential (FRP). However, you have requested to register this patient as a female not of reproductive potential (FNRP). Please contact the Call Center to discuss reasons for this request and complete this patient's registration.	
Patient, FCBP 3310071967	Post-therapy Pregnancy Test Results are required at completion of therapy and 30 days after completion of therapy. One or both of these post-therapy Pregnancy Test Results are now due.	Take Action

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iPLEDGE Terms of Use

IPLEDGE TERMS OF USE

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.ipledgeprogram.com (the "**Site**"). The "**iPLEDGE Website**" is a Registered User-only account portal available through the Site which enables Registered Users to participate with a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"**Registered Users**" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "**Patients**" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program.

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Safety Notice

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

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FDA REMS Submission

Designee Screens Inventory

iPLEDGE Program

Revised: May 2016

Designee Screens Inventory:

The following are Designee specific screens and shared Designee and Prescriber screens. Only the initial screen display of the shared Designee and Prescriber screens are included here; complete screen sequences are listed under the Prescriber Screen Inventory document.

- Common – Header and Footer
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- Designee Activation Complete
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- Update My Information – (Designee Change Password and Change DOPS)
- Designee Acting on Behalf of Prescriber – Update My Information (Prescriber)
- Designee Acting on Behalf of Prescriber – Accept Patient
- Designee Acting on Behalf of Prescriber – Manage Delegates/Designees*
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- Terms of Use
- Safety Notice

*See additional feature web pages under Prescriber Web Pages

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Common – iPLEDGE Web page header/footer

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Designee Home Page:

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Select Prescriber

SAFETY NOTICE

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

- You must select a Prescriber

Select the radio button next to the Prescriber, then select continue to work on the Prescriber's behalf.

	First Name	Last Name	Suffix
○	iPLEDGE	Prescriber	MD

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Continue Cancel

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Designee Activation

Compliance Notice

Isotretinoin is teratogenic and must not be used by pregnant women. The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. With these program goals in mind, iPLEDGE data is routinely analyzed to identify actions of non-compliance.

Information entered into the iPLEDGE system is considered part of the patient's medical record, and can be used to investigate suspected non-compliance. Verified non-compliance with regard to the iPLEDGE Program requirements can result in removal from the iPLEDGE Program.

Prescribers are responsible for all iPLEDGE activities performed by their Office Staff Designees. If an Office Staff Designee is found to be non-compliant with iPLEDGE, resulting actions, including possible removal from the iPLEDGE Program, can include both the Designee and the Prescriber.

Verified non-compliance may be reported to the FDA.

- I acknowledge the statements above.
- I do not acknowledge the statements above.

Submit

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Designee Activation Complete

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Designee Activation Complete

You are now activated in the system.

You may now act on behalf of a prescriber.

Current Program Status: Attested

Status Expires: 5/26/2016

Finish

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Designee Acting on Behalf of Prescriber - Selected Prescriber Verification

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Selected Prescriber Verification

You are currently working on behalf of **iPLEDGE Prescriber, MD**.

If you wish to continue select the Manage Patients button below.

You may also select a button from the menu at the left to perform another task.

To select a different prescriber, click on the Select A Different Prescriber button below.

Select A Different Prescriber

Manage Patients | Action Required List

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Designee Acting on Behalf of Prescriber – Register New Patient

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Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification Number | Finish

Determine Patient Category:

Select Patient Category.

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)
- Patient is Male

Continue Cancel

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Designee – About Isotretinoin

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About Isotretinoin

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

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About iPLEDGE

The iPLEDGE program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a **SINGLE** pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPLEDGE Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of childbearing potential. The iPLEDGE Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPLEDGE system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mIU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

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Designee Acting on Behalf of Prescriber – Manage Patients

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Manage Patients

Search by Last Name: [ ] Search Clear

☐ Include Past Patients in search

Select the radio button next to each Patient, then select an action from the buttons found below this table.

	Name	Identification	Date of Birth	FRP	Status	Address
◉	Patient, FCBP	3911101993	11/10/1993	Yes	Registered	123 Test Test
○	Patient, Female	3304041914	04/04/1914	No	Qualified to Receive Drug	123 Test Drive Blue Bell
○	Patient, Female	3304181997	04/18/1997	Yes	Required to Demonstrate Comprehension	123 Blue Moon St. Blue Bell
○	Patient, iPLEDGE	3011111992	11/11/1992	Yes	Confirmed Positive	123 Test Testing
○	Patient, iPledge	3104181997	04/18/1997	Yes	Registered	123 Test Drive Blue Bell
○	Patient, iPledge	3301011991	01/01/1991	Yes	Qualified to Receive Drug	123 Test Street Blue Bell
○	Patient, iPledge	3304181974	04/18/1977	Yes	Registered	123 Test Drive Blue Bell
○	Patient, iPLEDGE	3306061966	06/06/1966	Yes	Registered	123 FNRP Street Blue Bell

1 2

Select Action:

Edit Patient Demographics	Check Patient Status	Discontinue Patient
Confirm Patient Counseling	Re-Register Patient	Report Pregnancy
Edit Patient Contraception	Change Patient Type	Request Exemption
Post-therapy Pregnancy Test	Report Tanner Stage Change	

If you select a patient, and one of the action buttons is disabled, this is because either you or your patient is not in the required iPLEDGE Program status and the action is not allowed in that status.

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Prescriber Information

About Prescriber Information
The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. The resources below present the program requirements and help you prepare and plan treatments with patients during the course of isotretinoin therapy.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.
To order Educational Materials, please click here.

Patient Information:

- Mylan Amnesteem Medication Guide
- Teva Claravis Medication Guide
- Ranbaxy Sotret Medication Guide
- VersaPharm Myorisan Medication Guide
- Ranbaxy Absorica Medication Guide
- Dr. Reddy's Zenatane Medication Guide
- The iPLEDGE Program Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- The iPLEDGE Program Guide to Isotretinoin For Male Patients and Female Patients Who Cannot Get Pregnant
- The iPLEDGE Program Birth Control Workbook (for patients)
- The iPLEDGE Program Contraception Referral Form and Contraception Counseling Guide
- Isotretinoin Contraception Referral Form
- Patient Flowchart

Prescriber Information:

- The iPLEDGE Program Patient Introductory Brochure
- The Guide to Best Practices for the iPLEDGE Program
- The iPLEDGE Program Prescriber Contraception Counseling Guide
- Prescriber Checklist for Female Patients of Reproductive Potential
- Prescriber Checklist for Male Patients and Female Patients Who Cannot Get Pregnant
- Recognizing Psychiatric Disorders in Adolescents and Young Adults A Guide for Prescribers of Isotretinoin
- Teva Claravis Package Insert
- Mylan Amnesteem Package Insert
- Ranbaxy Sotret Package Insert
- VersaPharm Myorisan Package Insert
- Ranbaxy Absorica Package Insert
- Dr. Reddy's Zenatane Package Insert
- Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)
- Patient Information/Informed Consent (for all patients)
- Prescriber Activation Instructions
- Prescriber Flowchart
- Instructions for Registering and Managing Office Staff Designees
- Lessons Learned About Leftover Medication
- Lessons Learned About Birth Control

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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Designee – Order Materials

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Order Materials

Enter quantities you would like to order

0 Checklists for Female Patients of Reproductive Potential *(1 to 3 pads of 50 tear sheets)*

0 Checklists for Male and Female Patients Not of Reproductive Potential *(1 to 3 pads of 50 tear sheets)*

0 DVD containing the videos "Be Prepared, Be Protected" and "Be Aware: The Risk of Pregnancy While on Isotretinoin" *(1 DVD)*

0 Patient Introductory Brochure *(1 to 3 packages of 5)*

0 Patient Educational Kit for Female Patients of Reproductive Potential *(1 to 10 kits)*

0 Patient Educational Kit for Males and Females Not of Reproductive Potential *(1 to 10 kits)*

0 Prescriber Educational Kit *(1 Kit)*

0 Spanish Patient Introductory Brochure *(1 to 3 packages of 3)*

0 Spanish Patient Educational Kit for Female Patients of Reproductive Potential *(1 to 10 kits)*

0 Spanish Patient Educational Kit for Males and Females Not of Reproductive Potential *(1 to 10 kits)*

Place Order

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Update My Information

Change Password

Change Date of Personal Significance

Edit Prescriber Demographics for : [Please Select Prescriber]

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Designee – Update My Information – Change Password

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Change Password

** denotes required field*

Old Password *

New Password *

Confirm New Password *

Save Changes

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Designee – Update My Information – Change DOPS

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Change Date of Personal Significance

Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the Call Center.

** denotes required field*

Password: *

Date of Personal Significance: (MM/DD/YYYY) / / *

Confirm Date of Personal Significance: (MM/DD/YYYY) / / *

Save Changes

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Designee Acting on Behalf of Prescriber – Update Contact Information - Edit Prescriber Demographics

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Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center.

** denotes required field*

First Name*	Last Name*	Middle Initial	Suffix	Specialty
iPLEDGE	Prescriber		MD	Derm

Address*
123 Test Drive
Suite 200

City*	State*	Zip*
Test City	KS	12345

Phone Number *	Fax Number	Email *
555-555-1212		marcio.spieker@ubc.com

Preferred method of communication *
U.S. Mail

Cancel | Save Changes

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Designee Acting on Behalf of Prescriber – Accept Patient

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Accept Patient

Please enter the Patient Identification Number of the patient transferring into your care, and click the Look Up button.

Patient Identification Number

[ ] Look Up

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Manage Delegates and Designees

Delegates

A prescriber can delegate another registered and activated iPLEDGE prescriber to cover for him/her during a scheduled absence (travel, vacation, etc.). This also can be used to delegate to another registered and activated prescriber in a multiple doctor practice where a patient may see any of the doctors in the office. Delegate status has an expiration date that can be set by the delegating prescriber.

Manage Delegates

Designees

A designee is a staff member in the prescriber's office. A registered designee may perform all patient functions on behalf of the prescriber. An office designee may support all the registered prescribers in a multi-physician practice and will also have rights for any patient of a delegate prescriber. Each office staff designee will only need to register once, even if they support several prescribers. Also, if a prescriber is not activated in the iPLEDGE system, neither the prescriber nor the designated office staff can register a patient. The prescriber is responsible for any actions of all designees under him/her.

Register New Designee

Manage Designees

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Designee - My Program Status

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Designee Program Status

Your Program Status:	Attested
Program status expiration date:	2/18/2016

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Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button

Zip | City | State

Search

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Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PRESCRIBER
C. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Action Required List

Based on the iPLEDGE Program requirements, listed below are actions that are required. Please provide the required information to ensure completion of all iPLEDGE Program requirements.

Name	Message	
Brown, Cindy 3301022009	Enter the initial post-therapy Pregnancy Test Results, due upon completion of therapy.	
Dough , Jane 3304041964	Patient has been in "Registered" status for over 60 days. If no activity occurs, the system will discontinue this patient on 01/03/2010.	

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iPLEDGE Terms of Use

IPLEDGE TERMS OF USE

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.ipledgeprogram.com (the "**Site**"). The "**iPLEDGE Website**" is a Registered User-only account portal available through the Site which enables Registered Users to participate with a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"**Registered Users**" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "**Patients**" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program.

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Safety Notice

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

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FDA REMS Submission

Public and Common Screens Inventory

iPLEDGE Program

Revised: May 2016

Public and Common Screens Inventory:

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- Public – Home Page
- Public – Office Staff Designee Registration - New Page
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- Prescriber Information
- Find a Participating Pharmacy
- FAQs
- Terms of Use
- Safety Notice
- Forgot Password? link
- User login timed out

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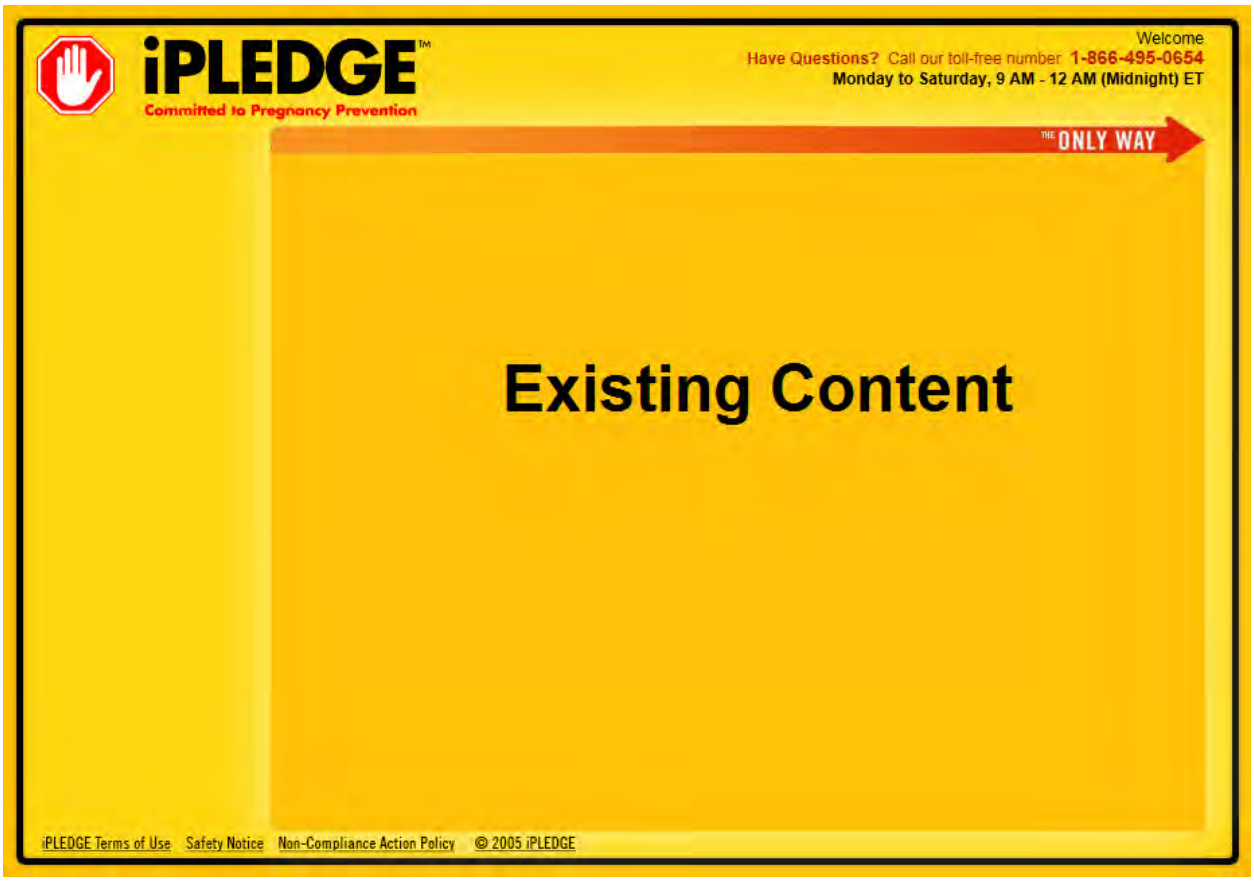
Common – iPLEDGE Web page header/footer



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Public Home Page

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Committed to Pregnancy Prevention

Welcome
Have Questions? Call our toll-free number 1-866-495-0654
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SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Login for registered users
Username:
Password:
I understand and will comply with:
- iPLEDGE Terms of Use
- Non-Compliance Action Policy

LOGIN
Forgot Password?

How to Report
Call our toll free number 1-866-495-0654 to report any of the following:
An Adverse Event: If you or someone you know has experienced an adverse event, please call 1-866-495-0654.
A Pregnancy: If you are an activated prescriber, report pregnancy results by logging in and clicking on "Manage Patients." Otherwise, please call 1-866-495-0654.

For lessons learned on birth control, please Click Here

Patient Registration Information
For information on becoming a registered iPLEDGE patient.
Patient Registration Information

Prescriber/Pharmacy/Designee Registration
Enter here to register in the iPLEDGE Program for the first time or to change data on your registration form.
For Prescribers | For Office Staff Designees
For Responsible Site Pharmacists

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Office Staff Designee Registration – New Page

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Office Staff Designee Registration

Office Staff Designees cannot register directly in the iPLEDGE Program.

All Designees must be registered in iPLEDGE by a Prescriber.

A Prescriber is a medical professional such as a doctor, physician assistant, or nurse practitioner who has prescribing privileges. If you believe you should be registered in the iPLEDGE Program as a Designee, please discuss with your sponsoring Prescriber.

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Patient Information

About Patient Information
Are you thinking about starting treatment with isotretinoin? You can learn more about isotretinoin and about the iPLEDGE Program by reading the introductory information brochure and the medication guide available below.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.

Patient Information:

- The iPLEDGE Program Patient Introductory Brochure
- Mylan Amnesteem Medication Guide
- Teva Claravis Medication Guide
- Ranbaxy Sotret Medication Guide
- VersaPharm Myorisan Medication Guide
- Ranbaxy Absorica Medication Guide
- Dr. Reddy's Zenatane Medication Guide

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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About Isotretinoin

Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.

INDICATIONS AND USAGE
Severe Recalcitrant Nodular Acne

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those female patients who are not pregnant, because isotretinoin can cause severe birth defects.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

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About iPLEDGE

The iPLEDGE Program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a **SINGLE** pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPLEDGE Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of childbearing potential. The iPLEDGE Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPLEDGE system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mIU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

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Prescriber Information

About Prescriber Information
The goals of the iPLEDGE Program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. The resources below present the program requirements and help you prepare and plan treatments with patients during the course of isotretinoin therapy.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.

Prescriber Information:

- The iPLEDGE Program Patient Introductory Brochure
- The Guide to Best Practices for the iPLEDGE Program
- VersaPharm Myorisan Package Insert
- Teva Claravis Package Insert
- Mylan Amnesteem Package Insert
- Ranbaxy Sotret Package Insert
- Ranbaxy Absorica Package Insert
- Dr. Reddy's Zenatane Package Insert
- Lessons Learned About Leftover Medication
- Lessons Learned About Birth Control

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button

Zip | City | State

Search

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iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PATIENT
C. PHARMACY
D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE
- How to resolve non-compliance with the Non-compliance Action Policy.

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- How can I login using my telephone?

  To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system will ask you to indicate which type of user you are (prescriber, patient, pharmacy or designee) and then prompt you to enter your user ID followed by the # button. You may be presented with additional prompts to confirm your user id.

  For each character of your username, press the key on the touch pad that corresponds to the number or letter. For example, the 2 button on the phone is used to enter either the number 2 or the letters A, B and C. The # must be pressed after all characters have been entered.

  For example, if your username is 12345, type 12345# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 2512345#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.

B. PATIENT
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- At what date and time does my prescription window close?

  Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may obtain your prescription. Patients will be provided with a message that states the ending date and time to obtain their prescription. This message has been updated to give patients the exact date and time when their prescription window will close. For example, the message will read:

  "You may obtain your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

  Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to obtain their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.

- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.

- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

C. PHARMACY
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HOW TO'S (click topics below for more information)

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- How can I find what is left to be completed before I am "Qualified to Receive Drug"?

  The iPLEDGE system provides updated information on your status in the program. This includes information on your current or most recent prescription window, as well as links directly to the next steps required to meet the program requirements to become "Qualified to Receive Drug". You can access this information by choosing the "My Program Status" button from the menu options.

- At what date and time does my prescription window close?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?

  Prior to filling the prescription, contact the pharmacy to ensure that they have enough product in stock to and dispense the prescription. The pharmacy must fill AND dispense the prescription within the prescription window. If the pharmacy cannot meet this deadline, the patient should go to another pharmacy. In most cases you will be able to re-start your window after your current prescription window expires. However, a potential lapse in treatment could result when a registered patient does not obtain the isotretinoin prescription within the prescription window.

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Frequently Asked Questions (FAQ)

- What are the steps to re-activate my registration?
- I either lost or forgot my password. How do I reset my password?
- How does a pharmacy obtain drug from a wholesaler?
- Can representatives at the iPLEDGE Program confirm a pharmacy's activation status?
- Do I need to see a patient's iPLEDGE ID card before I can fill and dispense an isotretinoin prescription?
- The patient's prescription was denied, will the system explain the reason?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.
- I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.
- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

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HOW TO'S (click topics below for more information)

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- I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.

  One of the following scenarios could be your situation:

  a. Updating the list of eligible pharmacies occurs once a day. If a pharmacy activates today, they will show up on tomorrow's list of eligible pharmacies. If your pharmacy was activated today (this includes cases where re-activation occurred due to an RSP change), your pharmacy will be able to order product the following day.

  b. There may be a discrepancy with how your DEA number is listed on the Current Master.xls. Provide your NCPDP number to your wholesalers as the wholesalers can review their lists by both the pharmacy NCPDP number and DEA numbers. Your wholesaler should perform this query and if you still are not listed, your wholesaler can contact the iPLEDGE for further assistance.

  c. For cases of DEA # discrepancies, you must have your DEA# corrected with NCPDP. You can do so by contacting NCPDP at 480-477-1000. NCPDP updates the iPLEDGE Program weekly.

- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

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1. Go to www.ipledgeprogram.com
2. Log in using your username (NCPDP#) and password.
3. Select "Update Personal Details" on the left side of the screen
4. Select "Change Date of Personal Significance"
5. Enter requested data and select "Save Changes"
6. Write down the new Date of Personal Significance

On the Phone

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Select the option to login, then enter your username (NCPDP#) and password when prompted
4. Select the option to change personal information
5. Select the option to change your Date of Personal Significance
6. Enter requested information when prompted
7. Write down the new Date of Personal Significance

Changing the RSP

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Press #0 to transfer to the call center, then press 1 at the prompt
4. Press 2 for pharmacies.
5. A call center agent will answer the call. Tell them that you want to change your pharmacy's RSP and that you need to be transferred to the technical help desk.

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the wholesaler as an eligible pharmacy to receive drug.

- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.

  Please contact the appropriate manufacturers' vendors listed below:

  Accutane (Roche): **1-800-526-0625**

  Amnesteem (Mylan): Stericycle at **1-800-796-9526**

  Claravis (Teva): MedTurn Inc. at **1-800-967-5952**

  Sotret (Ranbaxy): MedTurn Inc. at **1-817-868-5300**

  Myorisan (VersaPharm): **1-800-548-0700**

  Absorica (Ranbaxy): MedTurn Inc. at **1-817-868-5300**

  Zenatane (Dr. Reddy's): MedTurn Inc. at **1-800-967-5952**
- Can I accept isotretinoin prescriptions by phone, fax or email?

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- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

D. PRESCRIBER

- Please explain the registration process.
- We received new educational materials, when should we start to use them?
- How are iPLEDGE patient numbers assigned?

  Once a Prescriber performs the "Activation" step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber's address via UPS. The shipment includes two yellow kits (booklets) for females of reproductive potential and two green kits (booklets) for male patients or female patients who cannot get pregnant. Inside each kit you will find perforated, tear-off patient ID cards. Duplicates are provided in case the patient loses his or her ID card. The prescriber should separate off one card and give it to the patient along with the kit that contains the remaining duplicate ID cards. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. The prescriber should peel off the small tab that lists the patient's ID number, which is located on the same page containing the tear-off cards, and affix it in the patient's chart. For each new patient you must have a new patient educational kit available to provide to the patient.

- I either lost or forgot my password. How do I reset my password?
- Do I need to activate my registration annually?

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- I either lost or forgot my password. How do I reset my password?
- Do I need to activate my registration annually?
- What are the steps to re-activate my registration?
- Can prescribers edit their own (demographic) information?
- What is the difference between a Delegate and a Designee?
- How does an Office Staff Designee register and become affiliated to a Prescriber?

  Registration and affiliation is a two-step process.

  Registration - To register an Office Staff Designee, the **Prescriber** must login to the iPLEDGE website and click on "Manage Delegates/Designees" and then select "Register New Designee". The **Prescriber** must then complete the fields on the registration form, click on "Save and Print" at the bottom of the page, and sign the printout. The signed form must then be faxed to the number that appears on the form. Upon processing of the signed form, the Designee's Username and Password is sent via US Mail. Each designee should be registered only ONCE in the iPLEDGE system no matter how many prescribers he or she supports.

  Affiliation - Upon receipt of the Username and Password, the Designee may need to arrange with the Prescriber to affiliate the Designee to the Prescriber. To do this the Prescriber must login to the iPLEDGE website and click on "Manage Delegates/Designees" and then select "Manage Designees". The Prescriber must then enter the Designee's username into the Designee Username box and click on the "Add" button. The Designee's name will then appear on the "Your Designees" list and the Designee may begin to perform functions on behalf of the Prescriber. If the office does not have access to the iPLEDGE website, the prescriber can call 1-866-495-0654 (press 1, #0, 1, 4), to be assisted with Designee registration.

- How do I re-confirm a Patient of any type after their prescription window expires?
- Can Prescribers and Designees edit patient information?

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- Please explain the registration process.
- We received new educational materials, when should we start to use them?
- How are iPLEDGE patient numbers assigned?
- I either lost or forgot my password. How do I reset my password?
- Do I need to activate my registration annually?
- What are the steps to re-activate my registration?
- Can prescribers edit their own (demographic) information?
- What is the difference between a Delegate and a Designee?
- How does an Office Staff Designee register and become affiliated to a Prescriber?
- How do I re-confirm a Patient of any type after their prescription window expires?
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- What should I do with patients with a Lost to Follow Up status?
- Why do I need to discontinue a patient?
- When should I discontinue a patient?
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- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE Program?

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- How do I re-confirm a Patient of any type after their prescription window expires?

Prescribers must provide a new prescription and complete the qualification process again to ensure that all qualification criteria have been met and confirmed in the **iPLEDGE** system. System instructions are detailed below.

Females of Non-Reproductive Potential (FNRP) and MALES	Females of Reproductive Potential (FRP)
• To re-confirm a patient after their 30-day prescription window has expired, please do the following: - Go to the Manage Patient screen - Select the patient in the Manage Patient screen - Select the Confirm Patient Counseling button • The qualification process can start immediately after a patient's 30-day prescription window has expired or after a patient has successfully filled a prescription. • A new prescription must be provided to the patient	• To re-confirm an FRP after her 7-day prescription window has expired, please do the following: - Have the patient take a new pregnancy test - Go to the Manage Patient screen - Select the patient in the Manage Patient screen - Select the Confirm Patient Counseling button, enter the specimen collection date and the pregnancy test results. • A new prescription must be provided to the patient. **Note: If the Confirm Patient Counseling is grayed out, it means the patient is still within her 7-day prescription**

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- Can Prescribers and Designees edit patient information?
- Please show the iPLEDGE Program requirements.

Females of Reproductive Potential (FRP)

Initial 30 Days

Day 1 = Patient Registration and entry of screening pregnancy results into the iPLEDGE system. Screening pregnancy test can occur up to 30 days prior to patient registration. Screening pregnancy test may be conducted in the prescriber's office.

30 Days - Patient must be on two forms of contraception for 30 days after patient registration. The patient must wait at least 30 days after registration to receive the first prescription.

First Month

- As early as Day 31 = Once the patient's 30 day waiting period has ended, the patient is eligible for the office visit. A pregnancy test must occur during the first 5 days of the patient's menstrual cycle. This, and all subsequent monthly pregnancy tests, must be conducted at a CLIA certified laboratory.

Days 1 to 7 of the 7-day prescription window

- The prescriber must confirm counseling, enter the date of the pregnancy specimen collection and the pregnancy test results. **The pregnancy test specimen collection date starts the 7-day prescription window.**
- The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements. **Note: The patient cannot perform this function until the pregnancy test specimen collection date and test results have been entered into the system by the prescriber/designee.**

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- Discontinue the patient that has completed therapy. See "Why do I need to discontinue a patient?"
- The patient should not donate blood until she has been off isotretinoin therapy for at least 30 days.

Females of Non-Reproductive Potential (FNRP) and Males

Initial 30 Days

Day 1 = Patient Registration, eligible for the office visit and the prescriber has the ability to confirm counseling. There is no 30-day waiting period requirement.

Day 1

- The Confirmation Counseling Date. This date starts the 30-day prescription window.

Days 1 to 30

- The patient can fill and pick up the prescription.

Day 31

- The patient's 30-day prescription window is closed. There is no waiting period. The patient can re-qualify and have a new prescription filled immediately after the 30-day prescription window has expired or after successfully filling a prescription. A new prescription is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.

Each Subsequent Month (Through End of Therapy)

Day 1

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- Please show the iPLEDGE Program requirements.
- Why is the "Confirm Counseling" button not available for my patient on the web?

There are several reasons why the "Confirm Counseling" button is not available for a patient.

1. The patient is a Female of Reproductive Potential (FRP) and was registered in the last 30 days. See "Please show the iPLEDGE Program requirements".
2. The patient is a Female of Reproductive Potential (FRP) who missed the prescription window for her first prescription and must wait at least 19 days between pregnancy tests to start the qualification process for another prescription.
3. a) For females of reproductive potential, the patient is still in her prescription window.
   b) For females of non-reproductive potential and male patients, the patient is still in his/her 30-day prescription window, and has not yet filled a prescription.
4. The patient's program status is one of the following:
   a. Lost To Follow Up
   b. Confirmed Positive
   c. Reported Positive
   d. Inactive

If your patient is not eligible for the next prescription according to the program timelines, the "Confirm Counseling" activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapse, a new prescription window can be started (for example, the previous prescription window has expired) and the system will allow you to restart the qualification process.

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- Can Prescribers and Designees edit patient information?
- Please show the iPLEDGE Program requirements.
- Why is the "Confirm Counseling" button not available for my patient on the web?
- How does a patient become Lost to Follow Up?

  Patients become lost to follow up due to the following conditions:

  - Patient has been in a "Registered" status for greater than 90 days and the prescriber/designee has not interacted with the patient's record
  - Patient has been in a "Requires Confirmation" status for greater than 53 days and the prescriber/designee has not interacted with the patient's record
  - FRPs who are missing their pregnancy test at date of last dose
  - FRPs who are missing their final pregnancy test 30 days post treatment
- What should I do with patients with a Lost to Follow Up status?
- Why do I need to discontinue a patient?

  It is critical to discontinue the patient to accurately reflect the patient's iPLEDGE status. It is also critical to obtain the post-discontinuation pregnancy tests per the program requirements (pregnancy test at date of last dose and pregnancy test 30 days post treatment). Discontinuing the patients (additionally for FRPs, documenting the necessary post treatment pregnancy tests) will avert phone calls from the iPLEDGE Program to your office inquiring about the patient's status.
- When should I discontinue a patient?
- What are the steps to discontinue a Patient?
- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?

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- Why do I need to discontinue a patient?
- When should I discontinue a patient?

  Patients should be discontinued when the following occurs:

  - Patient completes treatment and is no longer taking the medication
  - Patient was never confirmed and did not receive a prescription from your office
  - Patient rescinded consent to participate

  Please note that when a FRP is discontinued, they must have a pregnancy test at date of last dose and a pregnancy test 30 days post treatment.

  Please see "What are the steps to discontinue a Patient?"
- What are the steps to discontinue a Patient?
- I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?

  To resume a patient's active status, you need to speak with an iPLEDGE representative for technical support. Call 1-866-495-0654 (press 1, #0, 1, 2) to begin this process. You should not make any changes in the system with this patient until instructed to do so by the technical support agent. When calling, please have all pregnancy test results available for Females of Reproductive Potential (FRP).
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.
- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start

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- What happens if a patient loses his or her iPLEDGE ID card?
- Do males or females of non-reproductive potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE Program?

  No, once the male patient or female of non-reproductive potential patient is registered, the prescriber can start the 30-day prescription window by going to the "manage patients" screen and confirming patient counseling. Male patients and females of non-reproductive potential do not have to answer questions each month in the iPLEDGE system; only females of reproductive potential need to do so. Males and females of non-reproductive potential do not need to use contraception to qualify for the iPLEDGE Program.

- Can pregnancy tests be conducted prior to the prescriber office visit?

  Yes, the pregnancy test can be done prior to the prescriber office visit. For females of reproductive potential, the initial screening pregnancy test (1st test) must be conducted on the date of registration or no more than 30 days prior to patient registration. For ongoing monthly pregnancy tests, the specimen must be collected and processed in a CLIA certified laboratory and the date of the specimen collection and the pregnancy test results must be entered to start the patient's 7-day prescription window.

  (See Package Insert for timing requirements). The date of the specimen collection for the pregnancy test is Day 1 of the 7-day prescription window for females of reproductive potential.

- Does a female of non-reproductive potential need to take pregnancy tests?

  No, only females of reproductive potential need to take pregnancy tests and answer monthly questions.

- How long does the patient need to wait between monthly pregnancy tests?

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- Does a Female of Reproductive potential need to be on birth control or another form of contraception if she chooses abstinence? Or, is abstinence an acceptable option for iPLEDGE?

  The program requirement for an FRP is to be on two effective forms of birth control unless the patient chooses to be abstinent. A patient choosing abstinence does not need to choose another form of birth control. The system will default the secondary choice of "none" if abstinence is listed as the primary form. However, a secondary choice can still be entered.

  Abstinence means an FRP will not have sex or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do especially if the patient is used to having sex. It is easier not to have sex when it is a lifestyle choice, such as a religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence). If the patient cannot commit completely to not having sex while taking isotretinoin, she must use 2 separate, effective forms of birth control at the same time. The only exceptions are if she has had surgery to remove her uterus (a hysterectomy) or both of her ovaries (bilateral oophorectomy), or if her doctor has medically confirmed that she is post-menopausal.

- What are acceptable primary forms of birth control?

  Females of Reproductive Potential (FRP) must use two forms of effective birth control together correctly all the time (of which one must be a Primary form):

  - For at least one month before starting isotretinoin
  - While taking isotretinoin - treatment usually lasts four to five months
  - For one month after the last dose of isotretinoin - for continued protection against pregnancy

  Effective forms of contraception include both primary and secondary forms of

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ovaries (bilateral oophorectomy), or if her doctor has medically confirmed that she is post-menopausal.

- What are acceptable primary forms of birth control?
- What forms of birth control are NOT acceptable for the iPLEDGE Program?

  You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

  - Birth control pills without estrogen (progesterone-only mini-pills)
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
- What if the primary forms of contraception are contraindicated for the patient?
- Please explain the data entry requirements for contraception.
- What happens if Females of Reproductive Potential (FRP) patients answer their comprehension questions incorrectly?

  If an FRP answers her questions incorrectly, she will be given an opportunity to answer another question on the same topic. If she gets this wrong, she will be directed to review the appropriate educational materials. She can, at a later time, login again and attempt to answer the questions correctly.
- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?
- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?

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- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?

  Patients can start a new prescription window as soon as the previous prescription window has expired. This would be 7 days for females of reproductive potential (with the exception of females of reproductive potential who miss their first prescription window and must wait at least 19 days between pregnancy tests) and either 30 days or the day after a prescription is filled for females of non-reproductive potential and male patients. All program requirements must be repeated to start the new prescription window. Prescriptions are limited to a maximum 30-day supply.

- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?

  Yes. The 30-day waiting period is required of all FRPs taking isotretinoin. There are no exceptions.

- How do I enter the pregnancy test results using Serum test versus urine tests?
- May I fax or phone in prescriptions to the pharmacy?
- How do I manage low-dose maintenance therapy for patients?

  All patients receiving isotretinoin, regardless of the dose prescribed, are required to have monthly office visits and new prescriptions written. No refills are permitted. For FRPs, monthly pregnancy tests must be conducted throughout treatment regardless of dose or duration. There are no exceptions. All patients receiving isotretinoin therapy must adhere to the requirements of the iPLEDGE program.

- Who needs to answer patient monthly comprehension questions?
- Can I download consent forms from www.ipledgeprogram.com?
- How can I order additional program materials?

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- What forms of birth control are NOT acceptable for the iPLEDGE Program?
- What if the primary forms of contraception are contraindicated for the patient?
- Please explain the data entry requirements for contraception.
- What happens if Females of Reproductive Potential (FRP) patients answer their comprehension questions incorrectly?
- The patient just filled and picked up his/her isotretinoin prescription, how much time is needed before the patient can get his/her next prescription?
- Does a new Female of Reproductive Potential (FRP) starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?
- How do I enter the pregnancy test results using Serum test versus urine tests?
- May I fax or phone in prescriptions to the pharmacy?
- How do I manage low-dose maintenance therapy for patients?
- Who needs to answer patient monthly comprehension questions?

  Females of reproductive potential must answer education questions to demonstrate their comprehension on a monthly basis by logging into the system (either by calling the automated telephone system at 1-866-495-0654 or accessing the website at http://www.ipledgeprogram.com/). Males and females of non-reproductive potential (FNRP) do not need to answer the monthly comprehension questions

- Can I download consent forms from www.ipledgeprogram.com?
- How can I order additional program materials?
- What if my office is excluded from HIPAA requirements?

E. ALL USERS

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E. ALL USERS

- Does the iPLEDGE Program have a Privacy Statement?

  Yes. Everyone who wants to take the prescription medication isotretinoin is required to register and participate in the iPLEDGE Program. In order to help you fulfill the requirements of the program, iPLEDGE must obtain personal information from you. Protecting your privacy is very important to us. The complete iPLEDGE Privacy Statement can be found at the bottom of home page at http://www.ipledgeprogram.com/ by choosing the "Privacy Statement" feature.

- What happens if a patient loses his or her iPLEDGE ID card?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?
- At what date and time does my prescription window close?
- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?
- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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- At what date and time does my prescription window close?

  Once all requirements are completed, and Females of Reproductive Potential have completed their comprehension questions successfully, the system will inform you that you may pick up your prescription. Patients will be provided with a message that states the ending date and time to pick up their prescription. This message has been updated to give patients the exact date and time when their window will close. For example, the message will read:

  "You may pick up your prescription anytime before 11:59 PM Eastern Time on 11/21/2015."

  Users using the automated phone system will hear the same message. Patients that are "Qualified to Receive Drug" may also use the "Program Status" feature to verify the ending date and time to fill and pick up their prescription. Please allow ample time, as the system works on Eastern Time and the pharmacy must obtain authorization from iPLEDGE before the prescription may be dispensed.

- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?

  Users can download the iPLEDGE materials from the website using Acrobat. The link to this free Acrobat download is available on any page that has materials available for download. The website has been updated to include additional documents for download and self-printing.

- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

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IPLEDGE TERMS OF USE

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.ipledgeprogram.com (the "**Site**"). The "**iPLEDGE Website**" is a Registered User-only account portal available through the Site which enables Registered Users to participate with a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"**Registered Users**" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "**Patients**" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program.

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Safety Notice

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

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Reference ID: 3956479

Public – Forgot Password

iPLEDGE™
Committed to Pregnancy Prevention

Welcome
Have Questions? Call our toll-free number 1-866-495-0654
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

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Forgot Password

* denotes required field

Username *

Submit

If you cannot remember your Username, please select your user type

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Common – User login timed out

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Login Required

Login for registered users

Username:

Password:

I understand and will comply with:

- iPLEDGE Terms of Use
- Non-Compliance Action Policy

Forgot Password? LOGIN

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FDA REMS Submission

Pharmacy Screens Inventory

iPLEDGE Program

Revised: May 2016

Pharmacy Screens Inventory:

- Common – Header and Footer
- Pharmacy Registration – from Public Home Page
- Pharmacy Home Page – Suspended Pharmacy Login
- Pharmacy Home Page – Registered or Activated Pharmacy whose activation expires within 30 days.
- Pharmacy Home Page – Activated Pharmacy not within 30 days of expiration.
- Activate Pharmacy Registration
- Pharmacy Information
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- Fill Prescription – Prescription fill denial
- Fill Prescription – Confirm Patient
- Fill Prescription – Request Authorization
- Fill Prescription – Authorized
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- Reverse Prescription – Forgot RMA? Link
- Reverse Prescription – Verify RMA
- Reverse Prescription – Reversed
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- Find Wholesaler
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Common – iPLEDGE Web page header/footer

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Pharmacy Registration – For Responsible Site Pharmacists (Button) from Public Home Page

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Pharmacy Registration

Please provide your pharmacy's NCPDP number and click the Lookup Info button. This will be used as your Username to identify you in the program and for you to login to the iPLEDGE system using the phone or internet site.

NCPDP Number [ ] Lookup Info

Enter or confirm your information

** denotes required field*

Responsible Site Pharmacist First Name * Responsible Site Pharmacist Last Name*

Responsible Site Pharmacist License *

Phone* Fax

Email

Preferred Method of Communication*

☐ This pharmacy orders isotretinoin directly from one or more of the manufacturers of isotretinoin

Click the Save and Print button below. This will present a print friendly registration form for your signature. After printing and signing, return the form to the address or fax number found on the form.

Save and Print

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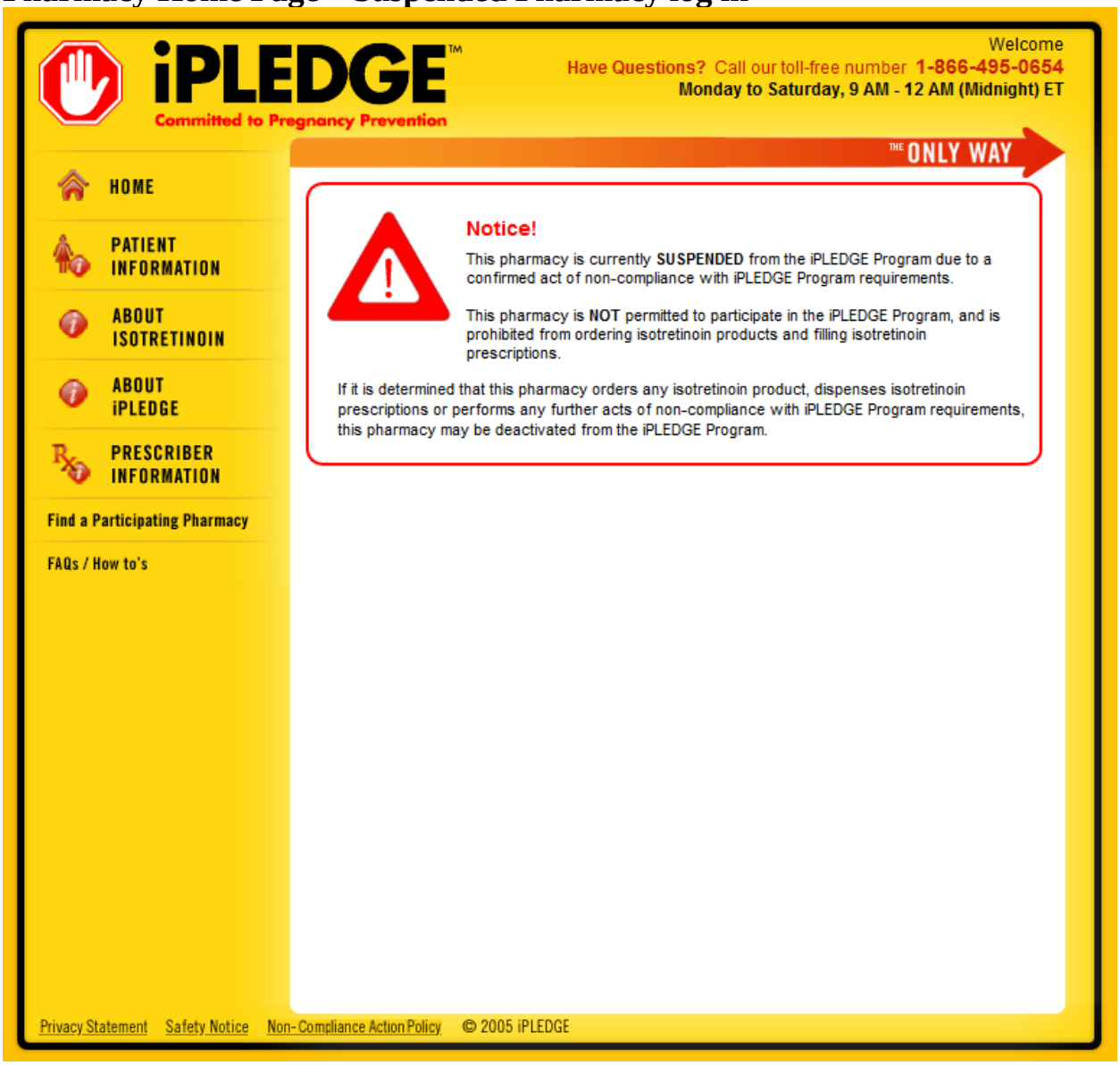
Reference ID: 3956479

Pharmacy Home Page – Suspended Pharmacy log in



UBC
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Pharmacy Home Page - Pharmacy in Program Status "Registered" or activated Pharmacy whose activation expires within 30 days.

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SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Activate My Registration

Follow the program steps to activate your pharmacy's registration.
Remember: you must activate your pharmacy's registration in the iPLEDGE Program annually. Please click the Activate button below to begin.

Activate

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
To report a pregnancy, please call 1-866-495-0654 .

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UBC
Reference ID: 3956479

Pharmacy Home Page - Activated Pharmacy not within 30 days of expiration.

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

Manage Prescriptions

Fill Prescription

How to Report

Call our toll free number 1-866-495-0654 to report any of the following:

An Adverse Event
If you or someone you know has experienced an adverse event, please call 1-866-495-0654 .

A Pregnancy
To report a pregnancy, please call 1-866-495-0654 .

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Pharmacy - Activate Pharmacy Registration (1 of 2)

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Activate Pharmacy Registration

After registration, the Responsible Site Pharmacist can only activate the pharmacy registration by affirming that they meet requirements and will comply with all iPLEDGE requirements by attesting to the following points:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I will train all pharmacists, who participate in the filling and dispensing of isotretinoin prescriptions, on the iPLEDGE Program requirements.
- I will comply and seek to ensure all pharmacists who participate in the filling and dispensing of isotretinoin prescriptions comply with the iPLEDGE Program requirements described in the booklet entitled The Pharmacist Guide for the iPLEDGE Program.
- I will obtain isotretinoin product only from iPLEDGE registered wholesalers.
- I will not sell, buy, borrow, loan or otherwise transfer isotretinoin in any manner to or from another pharmacy.
- I will return to the manufacturer (or delegate) any unused product if registration is revoked by the manufacturer or if the pharmacy chooses to not reactivate annually.
- I will not fill isotretinoin for any party other than a qualified patient.

○ I attest to the statements above

○ I do not attest to the statements above

Submit

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Pharmacy - Activate Pharmacy Registration (2 of 2)

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Pharmacy Activation Complete

You are now activated in the system.
You may now select any of the menu options to the left to begin using the system.

Current Program Status: Activated
Status Expires: 6/3/2016

Finish

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Pharmacy - Pharmacy Information

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Pharmacy Information

About reference materials
The goals of the iPLEDGE program are to prevent fetal exposure to isotretinoin and to inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions. The iPLEDGE program education materials present the program requirements for pharmacists and for patients.There are also patient and program guides available about contraception.

View Information Online
You can click on each link to view the material online. Upon clicking on a link, each file will be launched in a new browser window. To view these PDF files, you will need Acrobat® Reader®.
To order Educational Materials, please click here.

Patient Information:
- Mylan Amnesteem Medication Guide
- Teva Claravis Medication Guide
- Ranbaxy Sotret Medication Guide
- VersaPharm Myorisan Medication Guide
- Ranbaxy Absorica Medication Guide
- Dr. Reddy's Zenatane Medication Guide

Pharmacy Information:
- The Pharmacist Guide for the iPLEDGE Program
- The iPLEDGE Program Patient Introductory Brochure
- The iPLEDGE Program Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- The iPLEDGE Program Guide to Isotretinoin For Male Patients and Female Patients Who Cannot Get Pregnant
- The iPLEDGE Program Birth Control Workbook (for patients)
- The iPLEDGE Program Prescriber Contraception Counseling Guide
- Pharmacy Activation Instructions
- Pharmacy Flowchart
- Lessons Learned About Leftover Medication

Prescriber Information:
- Teva Claravis Package Insert
- Mylan Amnesteem Package Insert
- Ranbaxy Sotret Package Insert
- VersaPharm Myorisan Package Insert
- Ranbaxy Absorica Package Insert
- Dr. Reddy's Zenatane Package Insert

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

Product Name	Company	Phone Number
Amnesteem®	Mylan Pharmaceuticals Inc.	1-800-796-9526
Claravis®	Teva Pharmaceuticals USA.	1-800-227-7522
Sotret®	Ranbaxy Laboratories, Inc.	1-800-472-4467
Myorisan™	VersaPharm Incorporated	1-855-208-4645
Absorica™	Ranbaxy Laboratories, Inc	1-800-472-4467
Zenatane™	Dr. Reddy's Laboratories, Ltd.	1-888-375-3784

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Pharmacy - About Isotretinoin

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About Isotretinoin

CONTRAINDICATIONS AND WARNINGS

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following isotretinoin exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking isotretinoin, isotretinoin must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

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About iPLEDGE

The iPLEDGE Program is a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA. The program strives to ensure that:

- No female patient starts isotretinoin therapy if pregnant
- No female patient on isotretinoin therapy becomes pregnant

This enhanced program is a **SINGLE** pregnancy risk management program for prescribing and dispensing all isotretinoin products (brand and generic products). The iPLEDGE Program requires registration of all wholesalers distributing isotretinoin, all healthcare professionals prescribing isotretinoin, all pharmacies dispensing isotretinoin, and **all male and female** patients prescribed isotretinoin. This program is designed to create a verifiable link between the negative pregnancy test and the dispensing of the isotretinoin prescription to the female patient of childbearing potential. The iPLEDGE Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives his/her isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPLEDGE system that the patient has been counseled about the risks of isotretinoin.

There are also additional qualification criteria and monthly requirements for female patients of childbearing potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of childbearing potential selects and commits to use two forms of effective contraception simultaneously for one month before, during, and for one month after isotretinoin therapy. She must have 2 negative urine or blood (serum) pregnancy tests with a sensitivity of at least 25 mIU/ml before receiving the initial isotretinoin prescription. The first pregnancy test is a screening test and can be conducted in the prescriber's office. The second pregnancy test must be done in a CLIA-certified laboratory according to the package insert. Each month of therapy, the patient must have a negative result from a urine or blood (serum) pregnancy test conducted by a CLIA-certified laboratory prior to receiving each prescription.

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Pharmacy - Fill Prescription – Prescription fill denial

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Notice!

DO NOT FILL THIS PRESCRIPTION!

You are **NOT** authorized to fill this prescription. The iPLEDGE Program safety requirements are not currently met. Failure to adhere to this denial may result in this pharmacy being deactivated from the iPLEDGE Program.

Additional Information:

- Please ask the patient to contact their doctor.

Look Up Patient

** denotes required field*

To obtain authorization to fill and dispense a prescription (including additional fills for the same prescription), select the Obtain Prescription Authorization option below, enter the required information and click on the Look Up Patient button.

Obtain Prescription Authorization

Patient ID:* 1001031706

Date of Birth (MM/DD/YYYY)* 03/29/1988

Look up Patient | Clear Info | Cancel

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Pharmacy - Fill Prescription – Lookup Patient

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Look Up Patient

** denotes required field*

To obtain authorization to fill and dispense a prescription (including additional fills for the same prescription), select the Obtain Prescription Authorization option below, enter the required information and click on the Look Up Patient button.

Obtain Prescription Authorization

Patient ID:* Date of Birth (MM/DD/YYYY)*

Look up Patient | Clear Info | Cancel

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Pharmacy - Fill Prescription – Confirm Patient

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Confirm Patient

Patient ID: 7006031998
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

Back Continue Cancel

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Pharmacy – Fill Prescription – Request Authorization

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Request Authorization

Patient ID: 7006031998
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

** denotes required field*

Please select drug dispensed:*

- Absorica

Absorica™ is not substitutable with Generic Isotretinoin Capsules USP (Amnesteem®, Claravis®, Myorisan™, Sotret®, Zenatane™)

Generic Isotretinoin Capsules USP

- Amnesteem
- Claravis
- Myorisan
- Zenatane

Days Supply:* (Maximum 30)

Quantity Dispensed:*

Select Qty

Back | Continue | Cancel

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Pharmacy – Fill Prescription – Request Authorization

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Request Authorization

Patient ID: 7006031998
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

** denotes required field*

Please select drug dispensed:*

- Absorica

Absorica™ is not substitutable with Generic Isotretinoin Capsules USP (Amnesteem®, Claravis®, Myorisan™, Sotret®, Zenatane™)

Generic Isotretinoin Capsules USP

- Amnesteem
- Claravis
- Myorisan
- Zenatane

Please select radio button above.

Select Qty

Back | Continue | Cancel

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Pharmacy – Fill Prescription – Authorized

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Fill Prescription

Look Up Patient | Confirm Patient | Request Authorization | Prescription Authorization

Prescription Authorization

Patient ID: 7006031998
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

RMA: 609545705561

AUTHORIZED to be dispensed until 11:59 PM Eastern Time on 6/9/2015.

Pharmacy Instructions

Risk Management Authorization (RMA) number is **609545705561**.
Please write the RMA number on the prescription.

The Prescription MUST be dispensed to the patient by 11:59 PM Eastern Time on 6/9/2015.
Please write this date on the prescription bag sticker.

If the prescription is not dispensed, you must return it to stock and you must reverse the authorization in the iPLEDGE system using the Reverse Prescription page.

Current Prescription Authorization(s):

```
Absorica 20 mg capsules Ranbaxy 10631-0116-31
Days Supply: 30
Quantity dispensed: 30

Record RMA on prescription: 609545705561
Record on prescription bag: 6/9/2015 11:59 PM EST
```

Finish | Enter additional fill for same Prescription

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UBC
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Pharmacy – Reverse Prescription

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Pharmacy Reverse Prescription

Reverse Prescription Authorization | Verify Risk Management Authorization (RMA) and Patient | Reversal Authorization

Reverse Prescription Authorization

** denotes required field*

To reverse an authorized prescription, enter the Risk Management Authorization (RMA) number, and click on the Continue button.

Risk Management Authorization (RMA) number:*

Continue Cancel

Forgot the RMA number? Look it up here.

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Pharmacy – Reverse Prescription
(Forgot the RMA number? link selected)

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Pharmacy Reverse Prescription

Reverse Prescription Authorization | Verify Risk Management Authorization (RMA) and Patient | Reversal Authorization

Reverse Prescription Authorization
** denotes required field*

To reverse an authorized prescription, enter the Risk Management Authorization (RMA) number, and click on the Continue button.

Risk Management Authorization (RMA) number:*

Continue Cancel

Select the radio button next to the RMA, and click the Continue button above.

	RMA	Patient Name	Patient Id	Date of Birth	Date Processed
○	500638502564	iPLEDGE Patient	7006031998	06/03/1998	May 27 2015 11:00AM
○	809035600164	iPLEDGE Patient	7006031997	06/03/1997	May 27 2015 10:46AM
○	201613902460	Ipledge Test2	7006021994	06/02/1994	May 25 2015 1:53PM
○	504513000267	Giga Patient1	7006011996	06/01/1996	Apr 2 2015 11:02AM
○	129211710303	Post Test	1110211961	10/21/1961	Sep 15 2014 1:50PM
○	324902310806	FEMALE FCBP	3010201970	10/20/1970	Sep 10 2014 12:42PM
○	629294702289	Male Patient	3008281968	08/28/1968	Aug 29 2014 8:31AM
○	610063310703	Female Patient	3010161991	10/16/1991	Aug 26 2014 11:36AM
○	220916610801	Post Test	1110211961	10/21/1961	Aug 16 2014 1:31PM
○	326807917204	FCBP Patient	3310161986	10/16/1986	Aug 15 2014 1:33PM

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Pharmacy – Reverse Prescription – Verify RMA

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Pharmacy Reverse Prescription

Reverse Prescription Authorization | Verify Risk Management Authorization (RMA) and Patient | Reversal Authorization

Verify RMA and Patient Information

Risk Management Authorization (RMA) Number: 610063310703

Associated Product(s):

Product	Qty	Supply
00378-6611-93	30	30

Patient ID: 3010161991
Date of Birth: 10/16/1991
Patient Name: Female Patient

Back Continue Cancel

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Pharmacy – Reverse Prescription

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Reverse Prescription Authorization | Verify Risk Management Authorization (RMA) and Patient | Reversal Authorization

- Prescription Reversed

Reverse Prescription Authorization

Risk Management Authorization RMA number 610063310703 has been **REVERSED**. The Prescription can be returned to stock.

Finished

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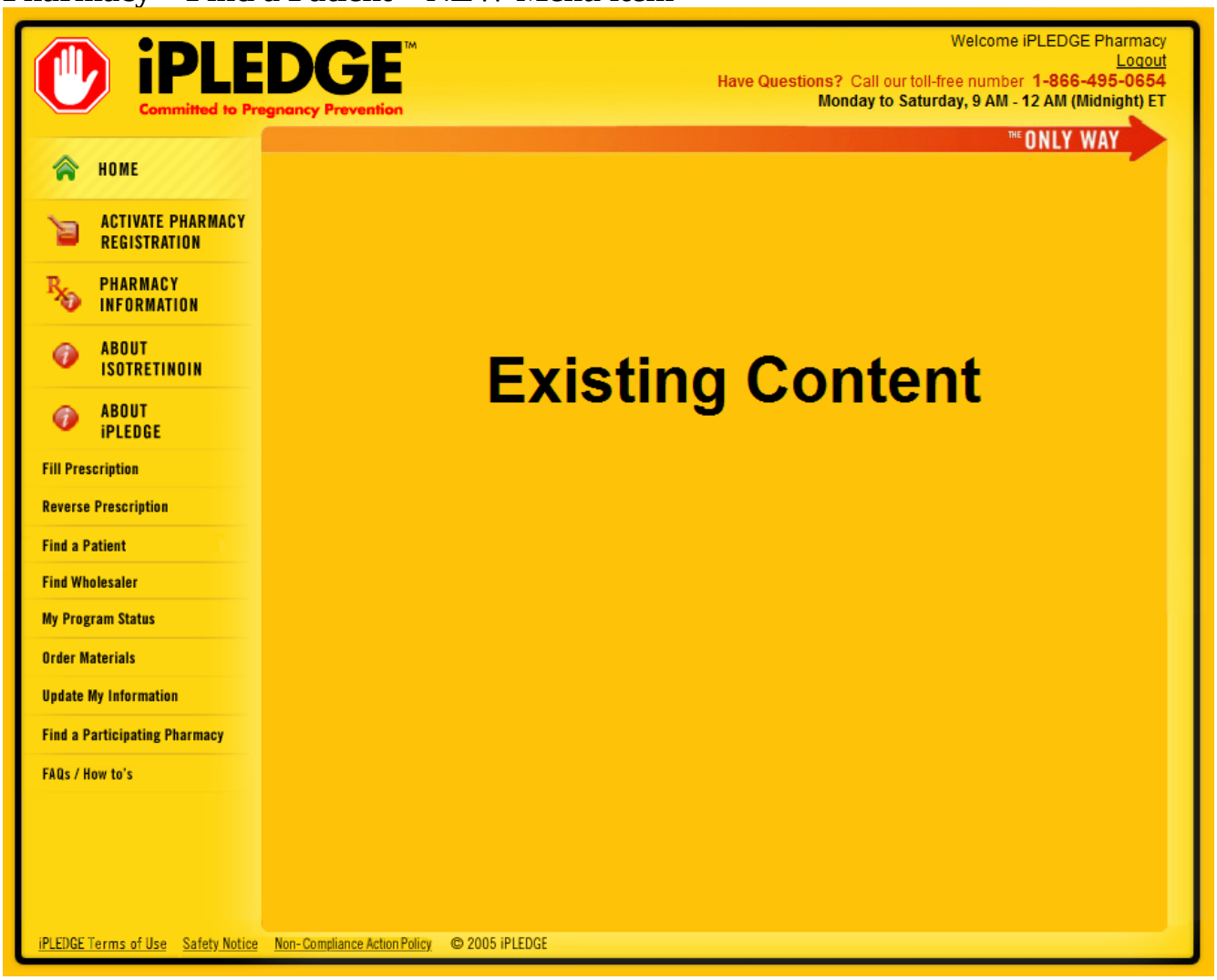
Pharmacy – Find a Patient – NEW Menu item



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Pharmacy – Find a Patient – NEW Screen

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Find a Patient

Notice:
The Patient information search results displayed below are for the patient for whom you have requested to obtain a Risk Management Authorization (RMA) Number.

Please enter PatientID and a Date Range
** denotes required field*

Patient Identification Number:*
3306131913

Date Range:*
From: Jan / 01 / 2012 To: Jun / 24 / 2013

Search

PatientID: 3306131913
Patient Name: Mary iPledge FCBP **Date of Birth:** 04/25/1989

RMA	Result	Date Authorized or Denied	Date Reversed
511331901365	Authorized	Jun 13 2013 10:00AM	n/a
Requested	Denied	May 05 2013 11:00AM	n/a
127695802132	Reversed	Mar 29 2013 1:06PM	Mar 29 2013 2:03PM
127790205037	Reversed	Mar 29 2013 10:29AM	Mar 29 2013 11:15AM
611196300737	Authorized	Mar 19 2013 12:03PM	n/a
Requested	Denied	Nov 21 2013 11:15AM	n/a
819675611100	Authorized	Oct 17 2012 10:09AM	n/a
Requested	Denied	Oct 17 2012 10:05AM	n/a
815765615108	Reversed	Oct 17 2012 10:03AM	Oct 17 2012 12:03PM
814262413707	Authorized	Oct 16 2012 2:46PM	n/a

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Pharmacy – Find Wholesaler

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Find Wholesaler

Please enter any or all search criteria and click the Search button

Wholesaler Name	Zip	City	State

Search

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Pharmacy – My Program Status

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Pharmacy Program Status

Your Program Status:	Activated
Program status expiration date:	6/3/2016

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Pharmacy - Order Materials

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Order Materials

Enter quantities you would like to order

0 The iPLEDGE Program Pharmacy Educational Kit, including flowchart *(1 kit)*

0 Patient Introductory Brochure *(1 to 3 packages of 5)*

0 Prescription Bag Stickers *(1 to 3 units of 100 stickers each)*

0 The iPLEDGE Program Prescriber Contraception Counseling Guide *(1 guide)*

Place Order

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Pharmacy – Update My Information

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Update My Information

Change Password

Change Date of Personal Significance

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Pharmacy - Update My Information – Change Password

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Change Password

** denotes required field*

Old Password *
New Password *
Confirm New Password *

Save Changes

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Pharmacy – Update My Information – Change DOPS

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Change Date of Personal Significance

Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the Call Center.
** denotes required field*

Password: *

Date of Personal Significance: (MM/DD/YYYY) / / *

Confirm Date of Personal Significance: (MM/DD/YYYY) / / *

Save Changes

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Pharmacy - Find a Participating Pharmacy

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Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button

Zip | City | State

Search

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iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PHARMACY
C. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- How can I login using my telephone?

  To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system will ask you to indicate which type of user you are (prescriber, patient, pharmacy or designee) and then prompt you to enter your user ID followed by the # button. You may be presented with additional prompts to confirm your user id.

  For each character of your username, press the key on the touch pad that corresponds to the number or letter. For example, the 2 button on the phone is used to enter either the number 2 or the letters A, B and C. The # must be pressed after all characters have been entered.

  For example, if your username is 12345, type 12345# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 2512345#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.

B. PATIENT
C. PHARMACY
D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

- What are the steps to re-activate my registration?
- I either lost or forgot my password. How do I reset my password?
- How does a pharmacy obtain drug from a wholesaler?
- Can representatives at the iPLEDGE Program confirm a pharmacy's activation status?
- Do I need to see a patient's iPLEDGE ID card before I can fill and dispense an isotretinoin prescription?
- The patient's prescription was denied, will the system explain the reason?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?

  Prescribers, patients, and pharmacies can obtain a list of pharmacies using the "Find A Participating Pharmacy" feature.
- I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.
- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

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- I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.

  One of the following scenarios could be your situation:

  a. Updating the list of eligible pharmacies occurs once a day. If a pharmacy activates today, they will show up on tomorrow's list of eligible pharmacies. If your pharmacy was activated today (this includes cases where re-activation occurred due to an RSP change), your pharmacy will be able to order product the following day.

  b. There may be a discrepancy with how your DEA number is listed on the Current Master.xls. Provide your NCPDP number to your wholesalers as the wholesalers can review their lists by both the pharmacy NCPDP number and DEA numbers. Your wholesaler should perform this query and if you still are not listed, your wholesaler can contact the iPLEDGE for further assistance.

  c. For cases of DEA # discrepancies, you must have your DEA# corrected with NCPDP. You can do so by contacting NCPDP at 480-477-1000. NCPDP updates the iPLEDGE Program weekly.

- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.
- Can I accept isotretinoin prescriptions by phone, fax or email?

D. PRESCRIBER
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Frequently Asked Questions (FAQ)

1. Go to www.ipledgeprogram.com
2. Log in using your username (NCPDP#) and password.
3. Select "Update Personal Details" on the left side of the screen
4. Select "Change Date of Personal Significance"
5. Enter requested data and select "Save Changes"
6. Write down the new Date of Personal Significance

On the Phone

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Select the option to login, then enter your username (NCPDP#) and password when prompted
4. Select the option to change personal information
5. Select the option to change your Date of Personal Significance
6. Enter requested information when prompted
7. Write down the new Date of Personal Significance

Changing the RSP

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Press #0 to transfer to the call center, then press 1 at the prompt
4. Press 2 for pharmacies.
5. A call center agent will answer the call. Tell them that you want to change your pharmacy's RSP and that you need to be transferred to the technical help desk.

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Frequently Asked Questions (FAQ)

the wholesaler as an eligible pharmacy to receive drug.

- How do I change my responsible site pharmacist (RSP)?
- How do I process a prescription that is more than 120 capsules per month?
- Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?
- I have questions regarding product returns.

  Please contact the appropriate manufacturers' vendors listed below:

  Accutane (Roche): **1-800-526-0625**

  Amnesteem (Mylan): Stericycle at **1-800-796-9526**

  Claravis (Teva): MedTurn Inc. at **1-800-967-5952**

  Sotret (Ranbaxy): MedTurn Inc. at **1-817-868-5300**

  Myorisan (VersaPharm): **1-800-548-0700**

  Absorica (Ranbaxy): MedTurn Inc. at **1-817-868-5300**

  Zenatane (Dr. Reddy's): MedTurn Inc. at **1-800-967-5952**

- Can I accept isotretinoin prescriptions by phone, fax or email?

D. PRESCRIBER
E. ALL USERS

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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Frequently Asked Questions (FAQ)

E. ALL USERS

- Does the iPLEDGE Program have a Privacy Statement?

  Yes. Everyone who wants to take the prescription medication isotretinoin is required to register and participate in the iPLEDGE Program. In order to help you fulfill the requirements of the program, iPLEDGE must obtain personal information from you. Protecting your privacy is very important to us. The complete iPLEDGE Privacy Statement can be found at the bottom of home page at http://www.ipledgeprogram.com/ by choosing the "Privacy Statement" feature.

- What happens if a patient loses his or her iPLEDGE ID card?
- Where do I find a list of local pharmacies that participate in the iPLEDGE Program?
- What happens if the pharmacy does not have enough product in stock to fill and dispense a prescription within the prescription window?
- At what date and time does my prescription window close?
- Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?
- How can I download iPLEDGE materials?
- Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?
- I would like to submit something in writing to the iPLEDGE Program. Is there a mailing address I should use?

HOW TO'S (click topics below for more information)

A. NON-COMPLIANCE

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iPLEDGE Terms of Use

IPLEDGE TERMS OF USE

Version 2.0. Last Revised: 08/17/2015

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.ipledgeprogram.com (the "**Site**"). The "**iPLEDGE Website**" is a Registered User-only account portal available through the Site which enables Registered Users to participate with a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to isotretinoin through a special restricted distribution program approved by the FDA.

THIS SITE IS INTENDED FOR U.S. AUDIENCES ONLY. USERS WHO ACCESS THE SITE FROM OUTSIDE THE U.S. DO SO AT THEIR OWN INITIATIVE AND RISK AND ARE RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE LAWS.

"**Registered Users**" include Patients, Prescribers, Designated Agents, and Pharmacists who have signed up to participate in the iPLEDGE Program. "**Patients**" are patients that have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program.

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Pharmacy – Safety Notice

iPLEDGE™
Committed to Pregnancy Prevention

Welcome iPLEDGE Pharmacy
Logout
Have Questions? Call our toll-free number 1-866-495-0654
Monday to Saturday, 9 AM - 12 AM (Midnight) ET

THE ONLY WAY

- HOME
- ACTIVATE PHARMACY REGISTRATION
- PHARMACY INFORMATION
- ABOUT ISOTRETINOIN
- ABOUT iPLEDGE
- Fill Prescription
- Reverse Prescription
- Find Wholesaler
- My Program Status
- Order Materials
- Update My Information
- Find a Participating Pharmacy
- FAQs / How to's

Safety Notice

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions.

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Phoenix, AZ 85038

PHARMACY ACTIVATION INSTRUCTIONS

Enclosed is The iPLEDGE Program Pharmacist Isotretinoin Educational Kit. Once you receive your password and have reviewed the enclosed educational materials you can activate with the iPLEDGE Program via the web site or phone system. You will need your username (this is your NCPDP number) and your password. You must complete the activation process in order to obtain authorization to fill and dispense an isotretinoin prescription under the iPLEDGE Program. While you may activate either on the web site or the automated phone system, for ease of use it is recommended that you activate on the web site.

Activating On The Web Site

Go to **www.ipledgeprogram.com** and log in by entering your username (NCPDP number) and password. You will be directed to change your password and set your Date of Personal Significance after you log in. Your Date of Personal Significance is a date that is easily remembered and will be used to verify your identity if you need to contact the call center. The same Date of Personal Significance will be used by all pharmacists in your pharmacy when calling the call center. It is recommended that you select a date that will be known by the entire pharmacist staff at your pharmacy. You will be presented with the pharmacy home page after you have changed your password and set your Date of Personal Significance. Select the **"Activate"** button from the **"Activate My Registration"** section of the page. The system will guide you through the activation process.

Activating On The Telephone

Call **1-866-495-0654** and listen to the menu options. Select the option to log in and follow the prompts to enter your username (NCPDP number) and password. You will be directed to change your password and set your Date of Personal Significance after you log in. Your Date of Personal Significance is a date that is easily remembered and will be used to verify your identity if you need to contact the call center. The same Date of Personal Significance will be used by all pharmacists in your pharmacy when calling the call center. It is recommended that you select a date that will be known by the entire pharmacist staff at your pharmacy. You will be presented with the pharmacy menu options after you have changed your password and set your Date of Personal Significance. Select the option to **"Activate Your Pharmacy."** The system will guide you through the activation process.

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PRESCRIBER ACTIVATION INSTRUCTIONS

Enclosed is the iPLEDGE Program Prescriber Isotretinoin Educational Kit. Once you receive your username and password and have reviewed the enclosed educational materials, you can activate with the iPLEDGE Program via the web site or automated phone system. You will need your username and password to do this. You must complete the activation process in order to prescribe isotretinoin under the iPLEDGE Program and to receive Patient Educational Kits, which are required to register patients in the iPLEDGE Program. While you may activate either on the web site or automated phone system, for ease of use it is recommended that you activate on the web site.

Activating on the web site

Go to **www.ipledgeprogram.com** and log in by entering your username (DEA number or program generated username) and password. You will be directed to change your password and set your Date of Personal Significance after you log in. Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the call center. You will be presented with the prescriber home page after you have changed your password and set your Date of Personal Significance. Select the **"Activate"** button from the **"Activate My Registration"** section of the page. The system will guide you through the activation process.

Activating on the telephone

Call **1-866-495-0654** and listen to the menu options. Select the option to log in and follow the prompts. You will be directed to change your password and set your Date of Personal Significance after you log in. Your Date of Personal Significance is a date that you will be able to remember (such as an anniversary) and will be used to verify your identity if you need to contact the call center. You will be presented with the prescriber menu options after you have changed your password and set your Date of Personal Significance. Select the option to **"Activate Your Registration."** The system will guide you through the activation process.

Receiving Patient Educational Kits

You can expect to receive Patient Educational Kits once you have activated your registration in the system. These are shipped via standard ground transportation and arrive within 5 to 10 days. These are required to register patients in the iPLEDGE Program.

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TATIANA OUSSOVA
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