iPLEDGE Program Website Screenshots
FDA REMS Submission

Patient Screens Inventory

iPLEDGE Program

Revised: December 2016
**Patient Screens Inventory:**

**Table of Contents**

- Patient Registration from Public Home Page .................................................. 3
- Patient Home Page for Patient in Program Status “Required to Demonstrate Comprehension” ................................. 4
- Patient Home Page for Patient Not in Program Status “Required to Demonstrate Comprehension” ............................... 5
- Patient – Comprehension Questions- Did not fill Rx in previous window ............................................................... 6
- Patient – Comprehension Questions ......................................................................................................................... 7
- Patient – Comprehension Questions – Abstinence Confirmation .................................................................................. 8
- Patient – Comprehension Questions - Patient Contraception and First Month Questions ............................. 9
- Patient – Comprehension Questions – Primary (First Time): .................................................................................. 10
- Patient – Comprehension Questions – Barrier/Primary (First Time): ................................................................. 11
- Patient – Comprehension Questions – Primary (Subsequent): ............................................................................. 12
- Patient – Comprehension Questions – Barrier/Primary (Subsequent): ................................................................. 13
- Comprehension Questions – Sample Question ........................................................................................................... 14
- Patient – Comprehension Question - Correct Answer - SAMPLE: ................................................................. 15
- Patient – Comprehension Question - Incorrect Answer - SAMPLE: ........................................................................ 16
- Patient – Comprehension Test Results- SAMPLE: Results: Failed ................................................................. 17
- Patient – Comprehension Test Results- SAMPLE: Results: Passed ................................................................. 18
- Patient – Contraception Information: .................................................................................................................... 19
- Patient – Patient Information ................................................................................................................................. 20
- Patient - About Isotretinoin .................................................................................................................................. 21
- Patient - About iPLEDGE ........................................................................................................................................ 22
- Patient – Change Primary Prescriber ...................................................................................................................... 23
- Patient – Find a Participating Pharmacy .................................................................................................................. 24
- Patient – Update My Information ........................................................................................................................... 25
- Patient – Update My Information – Change Password .......................................................................................... 26
- Patient – Update My Information – Change DOPS .............................................................................................. 27
- Patient – Update My Information – Update Contact Information ........................................................................ 28
- Patient – My Program Status .................................................................................................................................. 29
- Patient – FAQs ......................................................................................................................................................... 30
- Patient – iPLEDGE Terms of Use .......................................................................................................................... 31
- Patient – Safety Notice........................................................................................................................................... 32
Patient Registration

Patients cannot register directly in the iPLEDGE Program. All Patients are registered in iPLEDGE by a Prescriber. A Prescriber is a medical professional such as a doctor. If you believe you should be registered in the iPLEDGE Program, please contact your Prescriber.
Patient Home Page for Patient in Program Status “Required to Demonstrate Comprehension”

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 the toxicity of isotretinoin, only a pharmacist registered with the PLEDGE Program can dispense isotretinoin only by registered pharmacies that meet the requirements of the PLEDGE Program. The pharmacist can dispense the drug to the patient as long as he or she has completed the PLEDGE Program.

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 have 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 causes 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 isotretinoin. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, heart, vision, lipids, allergy 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 insert for full prescribing and dispensing instructions.

Answer the Comprehension Questions Section:

The PLEDGE Program requires you to answer comprehension questions before every prescription. These questions will demonstrate your understanding of the PLEDGE Program requirements. If you choose to take the PLEDGE Program, you may not obtain your prescription until you have correctly answered the questions. You may use your PLEDGE educational kit as a resource as you 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.
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 PLEDGE®. Under this program, prescribers must be registered and activated with the PLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of PLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with PLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with PLEDGE.

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 pancytopenia cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking fluoxetine. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, heart, muscles, hearing, vision, and kidney. Severe 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 insert for full prescribing and dispensing instructions.

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.
Patient – Comprehension Questions- Did not fill Rx in previous window

Answer Your Questions

Before You Get Started

iPLEDGE Program has no record of you filling a prescription in your prescription window from [month day, year] through [month day, year]. 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 Program system by the Pharmacy. If the Pharmacy does not authorize the prescription in the iPLEDGE Program 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 Program sticker on your prescription bag. You may find a participating Pharmacy by using the Find a Pharmacy feature on the iPLEDGE Program website.
Patient – Comprehension Questions

Answer Your Questions

Please follow these two steps to demonstrate iPLEDGE Program comprehension.

Step 1: Birth Control Verification

Please enter the two methods of birth control that you are using. These must be the same two methods 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 Program 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 obtain your prescription once you have correctly answered these questions.

Continue
Patient – Comprehension Questions – Abstinence Confirmation

Birth Control Verification

All fields listed below are required unless otherwise indicated.

Please select your birth control methods click the Submit button:

Primary:
- Abstinence

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

If the patient selects abstinence, they will not be allowed to select a second method of birth control.
Patient – Comprehension Questions - Patient Contraception and First Month Questions

Birth Control Verification

All fields listed below are required unless otherwise indicated.
Please select your birth control method(s) click the Submit button.

Primary
Birth Control Pills

Secondary
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 isotretinoin Educational Kit for Female Patients Who Can Get Pregnant?

Yes
No

If yes, did you read
1. The Guide to Isotretinoin for Female Patients Who Can Get Pregnant?

Yes
No

2. The 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
Patient – Comprehension Questions – Primary (First Time):

Birth Control Verification

All fields listed below are required unless otherwise indicated. Please select your birth control methods click the Submit button.

Primary
- Birth Control Pills
- Hormonal Implant
  - Hormonal IUD
  - Non-hormonal IUD (Copper)
  - Tubal Sterilization
  - Male Vasectomy
  - Natural Family Planning
  - Hormonal Shot
  - Hormonal Vaginal Ring
  - Hormonal Skin Patch
  - Birth Control Pills (Combination Type)
  - Progesterone-only Mini-pills
  - Abstinence

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
Patient – Comprehension Questions – Barrier/Primary (First Time):

**Birth Control Verification**

All fields listed below are required unless otherwise indicated. Please select your birth control methods and click the Submit button.

**Primary**
- Birth Control Pills

**Secondary**
- Hormonal IUD
- Non-hormonal IUD (Copper)
- Tubal Sterilization
- Male Vasectomy
- Natural Family Planning
- Hormonal Shot
- Hormonal/Vaginal Ring
- Female Condom
- Hormonal Skin Patch
- Birth Control Pills (Combination Type)
- Progestaoron-only Mini-pills
- Male Later Condom
- Cervical Cap with a Spermicide
- Diaphragm with a Spermicide
- Vaginal Sponge
- Withdrawal

- 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**
Patient – Comprehension Questions – Primary (Subsequent):

**Birth Control Verification**

All fields listed below are required unless otherwise indicated.

Please select your birth control methods click the Submit button.

**Primary**

- Birth Control Pills
- Hormonal Implant
- Hormonal IUD
- Non-hormonal IUD (Copper)
- Tubal Sterilization
- Male Vasectomy
- Natural Family Planning
- Hormonal Shot
- Hormonal Vaginal Ring
- Hormonal Skin Patch
- Birth Control Pills (Combination Type)
- Progesterone-only Mini-pills
- Abstinence

Submit
Patient – Comprehension Questions – Barrier/Primary (Subsequent):

Birth Control Verification

All fields listed below are required unless otherwise indicated.
Please select your birth control methods and click the Submit button.

Primary
- Birth Control Pills

Secondary
- Hormonal IUD

Hormonal Implant
- What is important not to become pregnant while taking isotretinoin?

- Hormonal IUD
- Non-hormonal IUD (Copper)
- Tubal Sterilization
- Male Vasectomy
- Natural Family Planning
- Hormonal Shot
- Hormonal Vaginal Ring
- Female Condom
- Hormonal Skin Patch
- Birth Control Pills (Combination Type)
- Progesterone-only Mini-pills
- Male Latex Condom
- Cervical Cap with a Spermicide
- Diaphragm with a Spermicide
- Vaginal Sponge
- Withdrawal

- 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
Comprehension Questions – Sample Question

Comprehension Questions

Program Steps

You are in your third month of treatment, in order to get your isotretinoin prescription, you must:

- Have a urinalysis test for infection.
- Have a negative pregnancy test done in a laboratory, discuss birth control with your doctor and answer questions in the iPLEDGE Program system.

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.
Comprehension Questions

Correct: You have selected the right answer.

Condoms

If you use a lubricant with a male latex condom, it should be a water-based lubricant.

- True
- False

Finish
Comprehension Questions

Incorrect Answer: The correct answer is “Continue to use 2 effective methods of birth control together all the time.”

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 methods of birth control together all the time.
- Stop using your secondary method because you are not taking isotretinoin.
- Go for the pregnancy test at any time during the month.

Please do not use browser’s Refresh, Back or Forward buttons when answering the questions, or you may have to start again.
Patient – Comprehension Test Results- SAMPLE: Results: Failed

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 methods 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 the 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 goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.

Reference: The Guide to Isotretinoin For Female Patients Who Can Get Pregnant, What is the iPLEDGE Program (see page 4).

Please review the Educational Materials before you answer the questions again.
Patient – Comprehension Test Results- SAMPLE: Results: Passed

Comprehension Questions Results

- The questions are complete.
- You may obtain your prescription any time before 11:59P.M. Eastern Time on mdlyyyyy

Important Note:

If this is your last month of treatment:

- Remember to continue using the two methods 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 the home page
Patient – Contraception Information:

Contraception Information

- Safety Information About Isotretinoin
- Birth Control Workbook
- The Guide to Isotretinoin For Female Patients Who Can Get Pregnant
- iPLEDGE Program Birth Control Information Sheet/iPLEDGE Program Checklist
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:
- Guide to Isotretinoin for Female Patients Who Can Get Pregnant
- Birth Control Workbook
- iPLEDGE Program Birth Control Information Sheet/iPLEDGE Program Checklist
- Contraception Counseling Guide and Contraception Referral Form
- Isotretinoin Contraception Referral Form
- Guide to Isotretinoin for Male Patients and Female Patients Who Cannot Get Pregnant
- Safety Information About Isotretinoin
- Dr. Reddy’s Zenatane Medication Guide
- Mylan Amnesteem Medication Guide
- Ranbaxy Absorica Medication Guide
- Ranbaxy Soriatan Medication Guide
- Teva Claravis Medication Guide
- VersaPharm Myorisan Medication Guide

Manufacturers’ Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnesteem®</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1-800-796-9526</td>
</tr>
<tr>
<td>Claravis™</td>
<td>Teva Pharmaceuticals USA.</td>
<td>1-800-227-7522</td>
</tr>
<tr>
<td>Soriatan®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-406-7984</td>
</tr>
<tr>
<td>Myorisan®</td>
<td>VersaPharm Incorporated</td>
<td>1-877-254-4381</td>
</tr>
<tr>
<td>Absorica®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-406-7984</td>
</tr>
<tr>
<td>Zenatane™</td>
<td>Dr. Reddy’s Laboratories, Ltd.</td>
<td>1-888-375-3784</td>
</tr>
</tbody>
</table>
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, microtia), small or absent external auditory canals; eye abnormalities (including microphthalmia); facial dysmorphism, 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 iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.
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. This 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 reproductive 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 Program 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 reproductive potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of reproductive potential selects and commits to use two methods 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.

Each month, the prescriber must enter the female patient's pregnancy results and the 2 methods of contraception she has been using in the iPLEDGE Program system. The iPLEDGE Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPLEDGE Program system via the internet (www.ipledegprogram.com), telephone (1-866-495-5654) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.
Patient – Change Primary Prescriber

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

City

State

Zip Code

Search

Found

Jane Smith
Blue Bell, PA
215-354-3345

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
Patient – Update My Information

Update My Information

Change Password
Change Date of Personal Significance
Update Contact Information
Patient – Update My Information – Change Password

Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes
Patient – Update My Information – Change DOPS

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.

All fields below are required unless otherwise indicated.

Password

Date of Personal Significance: (MM/DD/YYYY)

Confirm Date of Personal Significance: (MM/DD/YYYY)

Save Changes
Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center.

All fields below are required unless otherwise indicated.

First Name: Grija

Last Name: Dodapaneni

Address: 920 Harvest Drive

City: Blue Bell

State: PA

Zip: 19422

Phone Number: 555-555-5555

Fax (Optional): 

Email (Optional): grija.dodapaneni@ubc.com

Preferred Method of Communication: Select

[Cancel] [Save Changes]
## Patient Program Status

**Name:** Jane Smith  
**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

<table>
<thead>
<tr>
<th></th>
<th>Sun</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>

- If you haven’t already, obtain your prescription. More...

**Key:**
- Green: Today or future day for an active 7 day window
- Pink: A 7 day window that has expired without prescription fill
- Yellow: A past day for a 7 day window
- Blue: Action may occur on this date or any date after

You may click on **underline** links to perform the required action.
Patient – FAQs

Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)
A. TECHNICAL ASSISTANCE
B. PATIENT
C. ALL USERS

iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2016 iPLEDGE
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.ipledegprogram.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. "Prescribers" are prescribers that prescribe restricted distribution drugs pursuant to the iPLEDGE Program. "Designated Agents" are persons designated by Prescribers to act on their behalf with the iPLEDGE Website. Pharmacists are pharmacists that utilize the iPLEDGE Website to verify a patient's enrollment in iPLEDGE and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site ("you" or "your") and the sponsors of the Site (iPLEDGE, "we", "us" and "our").

REGISTRATION AND ASSENT
Access to and use of the Site is conditioned upon your assent to these terms of use. You are deemed to have assented to these terms of use when you use any available page of the Site. You are deemed to have assented to these terms of use as applicable to the iPLEDGE Website, when you complete the online registration process required for Registered Users and indicate during the registration process that you accept these terms of use along with the Privacy Policy incorporated therein. You are deemed to have accepted these terms of use each time you access the Site and each time you use your login credentials to access the iPLEDGE Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these terms of use. These terms of use and the Privacy Policy are available during registration for the iPLEDGE Website and on various pages of the Site.

UPDATES
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 or 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, lips, 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.
FDA REMS Submission

Pharmacy Screens Inventory

iPLEDGE Program

Revised: June 2017
Pharmacy Screens Inventory:

Table of Contents

Pharmacy – Pharmacy Registration – For Responsible Site Pharmacists (Button) from Public Home Page 3
Pharmacy Home Page – Suspended Pharmacy log in Page ................................................................. 4
Pharmacy Home Page - Pharmacy in Program Status “Registered” or activated Pharmacy whose
activation expires within 30 days ........................................................................................................... 5
Pharmacy – Pharmacy Home Page – Activated Pharmacy not within 30 days of expiration .............. 6
Pharmacy – Activate Pharmacy Registration (1 of 2) ........................................................................ 7
Pharmacy – Activate Pharmacy Registration (2 of 2) ........................................................................ 8
Pharmacy – Pharmacy Information ................................................................................................. 9
Pharmacy – About Isotretinoin ...................................................................................................... 10
Pharmacy – About iPLEDGE .......................................................................................................... 11
Pharmacy – Fill Prescription – Prescription fill denial .................................................................. 12
Pharmacy – Fill Prescription – Lookup Patient ................................................................................ 13
Pharmacy – Fill Prescription – Confirm Patient .............................................................................. 14
Pharmacy – Fill Prescription – Request Authorization .................................................................. 15
Pharmacy – Fill Prescription – Request Authorization .................................................................. 16
Pharmacy – Fill Prescription – Authorized ..................................................................................... 17
Pharmacy – Reverse Prescription .................................................................................................... 18
Pharmacy – Reverse Prescription (Forgot the RMA number? link selected) ................................. 19
Pharmacy – Reverse Prescription – Verify RMA ............................................................................ 20
Pharmacy – Reverse Prescription .................................................................................................... 21
Pharmacy – Find a Patient .............................................................................................................. 22
Pharmacy – Find Wholesaler ........................................................................................................... 23
Pharmacy – My Program Status ..................................................................................................... 24
Pharmacy – Order Materials ............................................................................................................ 25
Pharmacy – Update My Information ............................................................................................... 26
Pharmacy – Update My Information – Change Password ............................................................... 27
Pharmacy – Update My Information – Change DOPS ..................................................................... 28
Pharmacy – Find a Participating Pharmacy .................................................................................... 29
Pharmacy – FAQs/How To’s ............................................................................................................ 30
Pharmacy – iPLEDGE Terms of Use ............................................................................................... 31
Pharmacy – Safety notice ................................................................................................................ 32
Pharmacy Registration – For Responsible Site Pharmacists (Button) from Public Home Page

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 Program system using the phone or internet site.

NCPDP Number: [Field]

Lookup Info

Enter or confirm your information. All fields listed below are required unless otherwise indicated.

Responsible Site Pharmacist First Name: [Field]

Responsible Site Pharmacist Last Name: [Field]

Responsible Site Pharmacist License: [Field]

Preferred Method of Communication:
- Email

Phone Number: [Field] Ext (Optional): [Field]

Email (Optional): [Field]

Fax (Optional): [Field]

☐ This pharmacy orders isotretinoin directly from one or more of the manufacturers of isotretinoin.

Can your pharmacy management system adjudicate claims?
- Yes

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
Notice!

This pharmacy is currently SUSPENDED from the iPLEDGE Program due to a confirmed act of non-compliance with iPLEDGE Program requirements.

This pharmacy is NOT permitted to participate in the iPLEDGE Program, and is prohibited from ordering isotretinoin and filling isotretinoin prescriptions.

If it is determined that the pharmacy orders any isotretinoin product, dispenses isotretinoin prescriptions or commits any further acts of Non-Compliance with iPLEDGE Program requirements, this pharmacy may be deactivated from the iPLEDGE Program.
Pharmacy Home Page - Pharmacy in Program Status “Registered” or activated Pharmacy whose activation expires within 30 days.

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 PLEDGE®. Under this program, prescribers must be registered and activated with the PLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of PLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with PLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with PLEDGE.

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, kidneys, allergic reactions, blood sugar, or blood 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 insert 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 PLEDGE 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.
Activate Pharmacy Registration

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.
- 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 Pharmacist Guide, specifically the ‘Key Information for Pharmacists’ section including the following dispensing information:
  - 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.
- I will only obtain isotretinoin 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 the pharmacy is deactivated by the iPLEDGE Program 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
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: MM/DD/YYYY

Finish
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 Adobe Acrobat Reader.

Patient Information:
- Medication Guides:
  - Dr. Reddy’s Zanaflexa Medication Guide
  - Mylan Annasheem Medication Guide
  - Ranbaxy Absorica Medication Guide
  - Ranbaxy Sotrel Medication Guide
  - Teva Claravis Medication Guide
  - Versapharm Morison Medication Guide

Pharmacy Information:
- Pharmacist Guide
- Patient Introductory Brochure
- Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant
- Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant
- Birth Control Workgroup
- Pharmacy Activation Instructions
- Pharmacy Flowchart
- Lessons Learned:
  - About Leftover Medication
  - About Birth Control
  - About Post-Treatment Pregnancy Testing

Prescriber Information:
- Package Inserts:
  - Dr. Reddy’s Zanaflexa Package Insert
  - Mylan Annasheem Package Insert
  - Ranbaxy Absorica Package Insert
  - Ranbaxy Sotrel Package Insert
  - Teva Claravis Package Insert
  - Versapharm Morison Package Insert

Manufacturers’ Toll-free Numbers
For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annasheem™</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1-800-796-8526</td>
</tr>
<tr>
<td>Claravis™</td>
<td>Teva Pharmaceuticals USA</td>
<td>1-800-227-7522</td>
</tr>
<tr>
<td>Sotrel™</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-406-7984</td>
</tr>
<tr>
<td>Myenfas™</td>
<td>Versapharm Incorporated</td>
<td>1-877-254-4381</td>
</tr>
<tr>
<td>Absorica™</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-406-7984</td>
</tr>
<tr>
<td>Zanaflexa™</td>
<td>Dr. Reddy’s Laboratories, Ltd.</td>
<td>1-888-375-3784</td>
</tr>
</tbody>
</table>
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, microtia, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficits); 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 PLEDGE®. Isotretinoin must only be prescribed by prescribers who are registered and activated with the PLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with the PLEDGE Program, and must only be dispensed to patients who are registered and meet all the requirements of the PLEDGE Program.
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 reproductive potential. The iPledge Program requires that all patients meet qualification criteria and monthly program requirements. Before the patient receives her or isotretinoin prescription each month, the prescriber must counsel the patient and document in the iPledge Program 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 reproductive potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of reproductive potential selects and commits to use two methods 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.

Each month, the prescriber must enter the female patient’s pregnancy results and the 2 methods of contraception she has been using in the iPledge Program system. The iPledge Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPledge Program system via the internet (www.ipledgeprogram.com), telephone (1-866-495-5554) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.
Pharmacy – Fill Prescription – Prescription fill denial

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.

You must re-access the iPLEDGE Program System and acquire an RMA for this patient prior to dispensing.

Additional Information:
- Please ask the patient to contact their doctor.

Look Up Patient

All fields below are required unless otherwise indicated.

To obtain authorization to fill and dispense a prescription (including additional strengths for the same patient), enter the required patient information and then click on the Look Up Patient button.

Obtain Prescription Authorization

Patient ID:
1001031706

Date Of Birth (MM/DD/YYYY):
03/25/1988

[Buttons: Cancel, Clear info, Look up Patient]
Pharmacy – Fill Prescription – Lookup Patient

Fill Prescription

Look Up Patient

All fields below are required unless otherwise indicated.

To obtain authorization to fill and dispense a prescription (including additional strengths for the same patient), enter the required patient information and then click on the Look Up Patient button.

Obtain Prescription Authorization

Patient ID:
1001031706

Data of Birth (MM/DD/YYYY):
03/29/1968

Cancel  Clear Info  Look up Patient

iPLEDGE Terms of Use  Safety Notice  Non-Compliance Action Policy  © 2016 iPLEDGE
Pharmacy – Fill Prescription – Confirm Patient

Fill Prescription

Confirm Patient

Patient ID: 7006031198
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

Cancel  Back  Continue
Pharmacy – Fill Prescription – Request Authorization

Request Authorization

Patient ID: 7006031998
Date of Birth: 06/03/1998
Patient Name: iPledge Patient

All fields below are required unless otherwise indicated.

Please select product dispensed:

Absorica® is not substitutable with Generic Isotretinoin Capsules USP (Amnesteem®, Claravis®, Myorsan®, Soriatane®, Zenatane®)
Generic Isotretinoin Capsules USP
- Amnesteem
- Claravis
- Myorsan
- Zenatane

To proceed, please click on the radio button above that conforms to your product selection

Days Supply (optional field):

Quantity Dispensed:
Select Qty

Cancel  Back  Continue
Pharmacy – Fill Prescription – Authorized

Fill Prescription

Look Up Patient

Confirm Patient

Request Authorization

Prescription Authorization

Patient ID: 7066031998
Date of Birth: 06/03/1998
Patient Name: iPLEDGE Patient

Pharmacy Instructions

It is recommended that the pharmacist write the date on the sticker and put the sticker on the prescription bag. Please write the RMA number(s) on the prescription or document it in your pharmacy management system for each patient's fill.

AUTHORIZED to be dispensed to the patient until 11:59 PM Eastern Time on 11/10/2016.

If the prescription is not dispensed by this date:

- Reverse the authorization in the iPLEDGE Program system using the Reverse Prescription process
- Return the product to stock

<table>
<thead>
<tr>
<th>RMA</th>
<th>Brand/Strength</th>
<th>Quantity</th>
<th>Days Supply</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>60954705561</td>
<td>Absorica 20 mg capsules Ranbaxy</td>
<td>30</td>
<td>30</td>
<td>10631-0118-31</td>
</tr>
<tr>
<td>609954705562</td>
<td>Absorica 40 mg capsules Ranbaxy</td>
<td>30</td>
<td>30</td>
<td>10631-0118-31</td>
</tr>
</tbody>
</table>

Showing 1 to 2 of 2 entries

Note: If more than one strength is required to achieve the desired dosage, an RMA must be obtained for each strength.

Obtain another RMA for additional strength Finish
Pharmacy – Reverse Prescription

Pharmacy Reverse Prescription

Reverse Prescription Authorization

All fields below are required unless otherwise indicated.

To reverse an authorized prescription, enter the Risk Management Authorization (RMA) number, and click on the Continue button. If multiple RMA's were obtained for this prescription, all RMA's must be reversed.

Risk Management Authorization (RMA) Number:

Forgot the RMA number? Look it up here.

Cancel	 Continue
Pharmacy – Reverse Prescription – Verify RMA

Pharmacy Reverse Prescription

Verify RMA and Patient Information

Risk Management Authorization (RMA) Number: 610063310703

Associated Product(s):

<table>
<thead>
<tr>
<th>Product</th>
<th>Qty</th>
<th>Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>00378-0611.93</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Patient ID: 3010161991
Date of Birth: 10/16/1991
Patient Name: Female Patient

Cancel  Back  Continue
Pharmacy Reverse Prescription

Reverse Prescription Authorization
Risk Management Authorization RMA number 6100633000793 has been REVERSED. The product can be returned to stock.
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 Patient ID and a Date Range

All fields below are required unless otherwise indicated.

Patient Identification Number: 3306131913

Date Range:

From: Jan / 01 / 2002 To: Jun / 24 / 2013

Search

Patient ID: 3306131913

Patient Name: Mary iPLEDGE FRP

Date of Birth: 04/25/1989

<table>
<thead>
<tr>
<th>RMA</th>
<th>Result</th>
<th>Date Authorized or Denied</th>
<th>Date Reversed</th>
</tr>
</thead>
<tbody>
<tr>
<td>127665802132</td>
<td>Revers</td>
<td>Mar 29 2013 1:36 PM</td>
<td>Mar 29 2013 2:33 PM</td>
</tr>
<tr>
<td>127708205437</td>
<td>Revers</td>
<td>Mar 29 2013 10:20 AM</td>
<td>Mar 29 2013 11:15 AM</td>
</tr>
<tr>
<td>511331931365</td>
<td>Author</td>
<td>Jun 13 2013 10:00 AM</td>
<td>n/a</td>
</tr>
<tr>
<td>611190300737</td>
<td>Author</td>
<td>Mar 19 2013 12:03 PM</td>
<td>n/a</td>
</tr>
<tr>
<td>814262413787</td>
<td>Author</td>
<td>Oct 16 2012 02:46 AM</td>
<td>n/a</td>
</tr>
<tr>
<td>815756515168</td>
<td>Revers</td>
<td>Oct 17 2012 10:03 AM</td>
<td>Oct 17 2012 12:03 PM</td>
</tr>
<tr>
<td>819675811100</td>
<td>Author</td>
<td>Oct 17 2012 10:00 AM</td>
<td>n/a</td>
</tr>
<tr>
<td>Requested</td>
<td>Denied</td>
<td>May 05 2013 11:00 AM</td>
<td>n/a</td>
</tr>
<tr>
<td>Requested</td>
<td>Denied</td>
<td>Nov 21 2013 11:15 AM</td>
<td>n/a</td>
</tr>
<tr>
<td>Requested</td>
<td>Denied</td>
<td>Oct 17 2012 10:05 AM</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Showing 1 to 10 of 10 entries

1 10

iPLEDGE Terms of Use  | Safety Notices  | Non-Compliance Action Policy  | © 2016 iPLEDGE
Pharmacy – Find Wholesaler

Find Wholesaler

Please enter any or all search criteria and click the Search button.

<table>
<thead>
<tr>
<th>Wholesaler Name</th>
<th>Zip</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
</table>

Search
Pharmacy – My Program Status

Pharmacy Program Status

Your Program Status: Activated
Program Status Expiration Date: MM/DD/YYYY
Pharmacy – Update My Information

Update My Information

- Change Password
- Change Date of Personal Significance
Pharmacy – Update My Information – Change Password

Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes
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.

All fields below are required unless otherwise indicated.

Password

Date of Personal Significance: (MM/DD/YYYY)

Confirm Date of Personal Significance: (MM/DD/YYYY)

Save Changes
Pharmacy – Find a Participating Pharmacy

Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button.

Zip  City  State

Search
Pharmacy – FAQs/How To’s

Frequently Asked Questions (FAQ)

IPLEDEGE PROGRAM (click topics below for more information)
A. TECHNICAL ASSISTANCE
B. PHARMACY
C. ALL USERS
Pharmacy – iPLEDGE Terms of Use

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.pledgeprogram.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. “Prescribers” are prescribers that prescribe restricted distribution drugs pursuant to the iPLEDGE Program. “Designated Agents” are persons designated by Prescribers to act on their behalf with the iPLEDGE Website. Pharmacists are pharmacists that utilize the iPLEDGE Website to verify a patient’s enrollment in iPLEDGE and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site (“you” or “your”) and the sponsors of the Site (“iPLEDGE” “we”, “us” and “our”).

REGISTRATION AND ASSENT

Access to and use of the Site is conditioned upon your assent to these Terms of Use. You are deemed to have assented to these Terms of Use as applicable to the iPLEDGE Website, when you complete the online registration processes required for Registered Users and indicate during the registration process that you accept these Terms of Use along with the Privacy Policy incorporated therein. You are deemed to have accepted these Terms of Use each time you access the Site and each time you use your login credentials to access the iPLEDGE Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these Terms of Use. These Terms of Use and the Privacy Policy are available during registration for the iPLEDGE Website and on various pages of the Site.

UPDATES

Last updated: 08/17/2015

Welcome [NCIPDF#] Logout

Have Questions? Call our toll-free number 1-866-495-0554

THE ONLY WAY
PHARMACY – 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 isotretinone. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, limbs, 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.
FDA REMS Submission

Designee Screens Inventory

iPLEDGE Program

Revised: December 2016
Desigee Screens Inventory:

The following are Desigee specific screens and shared Desigee and Prescriber screens. Only the initial screen display of the shared Desigee and Prescriber screens are included here; complete screen sequences are listed under the Prescriber Screen Inventory document.

Table of Contents

Desigee Screens Inventory: ................................................................. 2
Desigee – Desigee Home Page: ......................................................... 3
Desigee Activation - Compliance Notice ............................................. 4
Desigee Activation Complete ............................................................ 5
Desigee Acting on Behalf of Prescriber - Selected Prescriber Verification ......................................................... 6
Desigee Acting on Behalf of Prescriber – Register New Patient ......................... 7
Desigee – About Isotretinoin ............................................................. 8
Desigee – About iPLEDGE ............................................................... 9
Desigee Acting on Behalf of Prescriber – Manage Patients ......................... 10
Desigee – Prescriber Information ..................................................... 11
Desigee – Order Materials ............................................................... 12
Desigee – Update My Information .................................................... 13
Desigee – Update My Information – Change Password ......................... 14
Desigee – Update My Information – Change DOPS ............................... 15
Desigee Acting on Behalf of Prescriber – Update Contact Information - Edit Prescriber Demographics ......................................................... 16
Desigee Acting on Behalf of Prescriber – Accept Patient ......................... 17
Desigee Acting on Behalf of Prescriber – Manage Delegates/Designees ......................... 18
Desigee - My Program Status ........................................................... 19
Desigee – Find a Participating Pharmacy .......................................... 20
Desigee – FAQs/How To’s ............................................................... 21
Desigee – Action Required List ......................................................... 22
Desigee – iPLEDGE Terms of Use .................................................... 23
Desigee – Safety Notice ................................................................. 24
Select Prescriber

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, lips, 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.

• You must select a Prescriber

Select the radio button next to the Prescriber, then select Continue to work on the Prescriber’s behalf.

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Suffix</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPODGE</td>
<td>Prescriber</td>
<td>MD</td>
</tr>
</tbody>
</table>

Showing 1 to 1 of 1 entities

1 » 10 ▼

Cancel  Continue
Designee Activation - Compliance Notice

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 safety conditions. With these program goals in mind, iPLEDGE data are routinely analyzed to identify actions of Non-Compliance.

Information entered into the iPLEDGE Program 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 Permanent Deactivation from the iPLEDGE Program. Click here to view the Non-Compliance Action Policy.

Prescribers are responsible for all iPLEDGE Program activities performed by their office staff designees. If an office staff designee is found to be non-compliant in the iPLEDGE Program, resulting actions, including possible Permanent Deactivation 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
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: 08/01/2017

Finish
Designee Acting on Behalf of Prescriber - Selected Prescriber Verification

Selected Prescriber Verification

You are currently acting on behalf of [Prescriber Name].

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.
Designee Acting on Behalf of Prescriber – Register New Patient

Register New Patient

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 a Male

Cancel  Continue
Desigee – About Isotretinoin

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, ears, 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 atroiza microtia, small or absent external auditory canals); eye abnormalities (including microphthalmia), facial dysmorphism; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve defects); 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 PLEDGE®. Isotretinoin must only be prescribed by prescribers who are registered and activated with the PLEDGE Program. Isotretinoin must only be dispensed by a pharmacy registered and activated with PLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of PLEDGE.
About iPledge

The iPledge Program is a computer-based risk management program designed to facilitate the public health goal of eliminating 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 reproductive 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 Program 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 reproductive potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of reproductive potential seeks and commits to use two methods 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.

Each month, the prescriber must enter the female patient’s pregnancy results and the 2 methods of contraception she has been using in the iPledge Program system. The iPledge Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPledge Program via the internet (www.i pledgeprogram.com), telephone (1-866-495-0854) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.
Designee Acting on Behalf of Prescriber – Manage Patients
Prescriber Information

About Prescriber Information

The goals of the IPLEDGE Program are to prevent fetal exposure to isotretnoin and to inform prescribers, pharmacists, and patients about isotretinoin’s serious risks and labeling 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 manual 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:

- Patient Information Brochure
- Guide to Best Practices for the IPLEDGE Program
- Prescriber Communication Checklist
- Responsibly Prescribing Isotretinoin in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin
- Patient Information/Information Consent About Birth Defects (for female patients who can get pregnant)
- Patient Information/Information Consent (for all patients)
- Prescriber Checklist for Female Patients of Childbearing Potential
- Prescriber Checklist for Male Patients and Female Patients Who Cannot Get Pregnant
- Prescriber Kit

Lessons Learned:

- About Low-Risk Medication
- About Birth Control
- About Post Treatment Pregnancy Testing

- Package Inserts:
  - Atelaun pregnancy package insert
  - Isotretinoin pregnancy package insert
  - Retin-A (Ranbaxy) pregnancy package insert
  - Vertex/Ranbaxy pregnancy package insert
  - Sandoz (Abogen) pregnancy package insert
  - Dr Reddy's (Zoladex) pregnancy package insert

Patient Information:

- Guide to Information for Female Patients Who Can Get Pregnant
- Birth Control Workbook
- IPLEDGE Program Birth Control Information Sheet/IPLEDGE Program Checklist
- Contraception Counseling Guide
- Contraception Referral Form
- Initial Contraception Referral Form
- Guide to Information for Male Patients and Female Patients Who Cannot Get Pregnant
- Safety Information About Isotretinoin

- Medications Guides:
  - Atelaun Medication Guide
  - Isotretinoin Medication Guide
  - Retin-A (Ranbaxy) Medication Guide
  - Vertex/Ranbaxy Medication Guide
  - Sandoz (Abogen) Medication Guide
  - Dr Reddy's (Zoladex) Medication Guide

Manufacturers' Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnesteem®</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1-800-796-9526</td>
</tr>
<tr>
<td>Claravis™</td>
<td>Taro Pharmaceuticals USA</td>
<td>1-800-337-9526</td>
</tr>
<tr>
<td>Soriat®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-472-4667</td>
</tr>
<tr>
<td>Myorin®</td>
<td>VertexPharm Inc.</td>
<td>1-877-565-4581</td>
</tr>
<tr>
<td>Absorica®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-472-4667</td>
</tr>
<tr>
<td>Zanaflex™</td>
<td>Dr Reddy's Laboratories, Ltd.</td>
<td>1-888-375-2786</td>
</tr>
</tbody>
</table>
Designee – Order Materials

Order Materials

Enter quantities you would like to order

- [ ] iPledge Program Birth Control Information Sheet/iPledge Program Checklist
  (1 to 10 sheets)

- [ ] Prescribing checklist for Female Patients of Reproductive Potential
  (1 to 3 pads of 50 tear sheets)

- [ ] Prescribing checklist for Male Patients and Female Patients of Non-Reproductive Potential
  (1 to 3 pads of 50 tear sheets)

- [ ] Educational DVDs: Be Prepared, Be Protected and Be Aware: The Risk of Pregnancy while on
  Isotretinoin
  (1 DVD)

- [ ] Patient Introductory Brochure
  (1 to 3 packages of 5)

- [ ] Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant
  (1 to 10 kits)

- [ ] Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant
  (1 to 10 kits)

- [ ] Prescriber Isotretinoin Educational Kit
  (1 kit)

- [ ] Spanish Patient Introductory Brochure
  (1 to 3 packages of 5)

- [ ] Spanish Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant
  (1 to 10 kits)

- [ ] Spanish Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant
  (1 to 10 kits)

Place Order
Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes
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.

All fields below are required unless otherwise indicated.

Password

Date of Personal Significance (MM/DD/YYYY)

Confirm Date of Personal Significance (MM/DD/YYYY)

Save Changes
Designee Acting on Behalf of Prescriber – Update Contact Information - Edit Prescriber Demographics

Update Contact Information

Use this form to edit your contact information. To edit information not displayed on this form, please contact the Call Center. Enter or confirm your information. All fields below are required unless otherwise indicated.

First Name: Marcie
Last Name: Speiker
Suffix: MD
Specialty: Derm
Address: 123 Test Drive, Suite 200
City: Test City
State: KS
Zip: 12345
Phone Number: 555-555-1212
Fax Number (Optional): 
Preferred Method of Communication: Email
Email (Optional): marcie.speerker@ubc.com

Cancel  Save Changes
Designee Acting on Behalf of Prescriber – Accept Patient

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
Designee Acting on Behalf of Prescriber – Manage Delegates/Designees

Manage Delegates and Designees

Delegates

A prescriber can delegate another registered and activated iPLEDGE Program 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 some patient functions on behalf of the prescriber. An office designee may support some of 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 Program system, neither the prescriber nor the designated office staff can register a patient. The registered prescriber is responsible for all information entered and activities performed in the iPLEDGE Program by all designees under his/her supervision.

Register New Designee

Manage Designees
Desigee - My Program Status

Your Program Status: Attested
Program Status Expiration Date: MM/DD/YYYY

iPLEDGE Terms of Use  |  Safety Notice  |  Non-Compliance Action Policy  |  © 2015 iPLEDGE
Designee – Find a Participating Pharmacy

Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button.

Zip   City   State
   
Search
Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)
A. TECHNICAL ASSISTANCE
B. PRESCRIBER
C. ALL USERS
Desigee – Action Required List

**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.

<table>
<thead>
<tr>
<th>Name</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown, Cindy</td>
<td>Enter the initial post-therapy Pregnancy Test Results, due upon completion of therapy.</td>
</tr>
<tr>
<td>Brown, Sandy</td>
<td>One or both post-therapy Pregnancy Test Results due upon completion of therapy. (If 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.</td>
</tr>
<tr>
<td>Dough, Jane</td>
<td>Patient has been in ‘Registered’ status for over 60 days. If no activity occurs, the system will discontinue this patient on 01/23/2010.</td>
</tr>
<tr>
<td>Patient, FRP</td>
<td>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.</td>
</tr>
<tr>
<td>Patient, Test</td>
<td>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 (FRNP). Please contact the Call Center to discuss reasons for this request and complete this patient’s registration.</td>
</tr>
</tbody>
</table>

Showing 1 to 5 of 5 entries
iPLEDGE Terms of Use

iPLEDGE TERMS OF USE

Version 2.0, Last Revised: 08/17/2016

These Terms of Use apply to all visitors of the prescription drug risk management site located at http://www.iplegedprogram.com (the "Site"). The iPLEDGE Website is a Registered User-only account portal available through the Site which enables Registered Users to participate in 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. Prescribers are prescribers that prescribe restricted distribution drugs pursuant to the iPLEDGE Program. Designated Agents are persons designated by Prescribers to act on their behalf with the iPLEDGE Website. Pharmacists are pharmacists that utilize the iPLEDGE Website to verify a patient's enrollment in iPLEDGE and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site ("you" or "your") and the sponsors of the Site ("iPLEDGE", "we", "us" and "our").

REGISTRATION AND ASSENT

Access to and use of the Site is conditioned upon your assent to these Terms of Use. You are deemed to have assented to these Terms of Use when you use any available page of the Site. You are deemed to have assented to these Terms of Use as applicable to the iPLEDGE Website, when you complete the online registration processes required for Registered Users and indicate during the registration process that you accept these Terms of Use along with the Privacy Policy incorporated therein. You are deemed to have accepted these Terms of Use each time you access the Site and each time you use your login credentials to access the iPLEDGE Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these Terms of Use. These Terms of Use and the Privacy Policy are available during registration for the iPLEDGE Website and on various pages of the Site.

UPDATES

The iPLEDGE Website may be updated by the iPLEDGE sponsors from time to time with subsequent updates to these Terms of Use. In the event the iPLEDGE sponsors make changes to these Terms of Use, these changes will be posted to the iPLEDGE Website and will become effective as of their date of posting, with the new version of the Terms of Use available on the Website.

You may view a copy of the current version of these Terms of Use at http://www.iplegedprogram.com/terms-of-use. Before using the iPLEDGE Website, you should review the current version of these Terms of Use to ensure you are aware of any changes.

By accessing the iPLEDGE Website and/or using any portion of the Site, you accept all of the terms and conditions contained in these Terms of Use.
Designee – 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.
FDA REMS Submission

Prescriber Screens Inventory

iPLEDGE Program

Revised: June 2017
Prescriber Screens Inventory:

# Table of Contents

- Prescriber Registration – Invalid Identifiers DEA Message ................................................................. 8
- Prescriber Home Page – Activated Prescriber not within 30 days of expiration ........................................ 9
- Prescriber Home Page – Prescriber in Program Status “Registered” or activated Prescriber whose activation expires within 30 days ........................................................................................................ 10
- Prescriber - Prescriber Activation .................................................................................................................. 11
- Prescriber - Prescriber Activation - Compliance Notice .................................................................................. 12
- Prescriber - Prescriber Activation Complete ................................................................................................. 13
- Prescriber - Register New Patient – FRP .......................................................................................................... 14
- Prescriber - Register New Patient – FRP .......................................................................................................... 15
- Prescriber - Register New Patient – FRP .......................................................................................................... 16
- Prescriber - Register New Patient – FRP .......................................................................................................... 17
- Prescriber - Register New Patient – FRP .......................................................................................................... 18
- Prescriber - Register New Patient – FRP – Patient not unique ........................................................................ 19
- Prescriber - Register New Patient – FRP .......................................................................................................... 20
- Prescriber - Register New Patient – FRP .......................................................................................................... 21
- Prescriber – Register New Patient - FNRP ....................................................................................................... 22
- Prescriber - Register New Patient – FNRP – Acknowledgement .................................................................. 23
- Prescriber - Register New Patient – FNRP – Determine Patient Category Question 1 of 3 .......................... 24
- Prescriber - Register New Patient – FNRP – Determine Patient Category Question 2 of 3 .......................... 25
- Prescriber - Register New Patient – FNRP – Determine Patient Category Question 3 of 3 .......................... 26
- Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FNRP ... 27
- Prescriber - Register New Patient – FNRP – Patient Information ................................................................. 28
- Prescriber - Register New Patient – FNRP – Patient Information ................................................................. 29
- Prescriber - Register New Patient – FNRP – Patient Information Review ..................................................... 30
- Prescriber - Register New Patient – FNRP – Patient Identification Number ................................................ 31
- Prescriber - Register New Patient – FNRP – Finish ...................................................................................... 32
- Prescriber - Register New Patient – FNRP – Continue option to confirm FNRP ........................................... 33
- Prescriber - Register New Patient – FNRP – Confirm FNRP complete.......................................................... 34
- Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FRP ... 35
- Prescriber - Register New Patient – FNRP – Request FNRP Status ............................................................... 36
- Prescriber - Register New Patient – MALE ...................................................................................................... 37
- Prescriber - Register New Patient – MALE – Patient Information ................................................................. 38
- Prescriber - Register New Patient – MALE – Patient Information ................................................................. 39
| Prescriber - Register New Patient – MALE – Patient Information Review | .......................................................... 40 |
| Prescriber - Register New Patient – MALE – Patient Uniqueness – Override Code | .......................................................... 41 |
| Prescriber - Register New Patient – MALE – Identification Number Entry | .......................................................... 42 |
| Prescriber - Register New Patient – MALE – Finish | .......................................................... 43 |
| Prescriber - Register New Patient – MALE – Continue to Confirm after Finish | .......................................................... 44 |
| Prescriber - Register New Patient – MALE – Confirm complete | .......................................................... 45 |
| Prescriber – About Isotretinoin | .......................................................... 46 |
| Prescriber – About iPLEDGE | .......................................................... 47 |
| Prescriber - Manage Patients | .......................................................... 48 |
| Prescriber - Manage Patients – Request Exemption button | .......................................................... 49 |
| Prescriber - Manage Patients – Request Exemption Option Selected | .......................................................... 50 |
| Prescriber - Manage Patients – Report Tanner Stage Change button | .......................................................... 51 |
| Prescriber - Manage Patients – Status Column – Red info button - SAMPLE | .......................................................... 52 |
| Prescriber - Manage Patients – Edit Patient Demographics Button | .......................................................... 53 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Confirm | .......................................................... 54 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Contraception | .......................................................... 55 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Abstinence selected as Primary – Confirmation of Important Message | .......................................................... 56 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Did not fill Rx in previous window – Message | .......................................................... 57 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result | .......................................................... 58 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after closing of popup message) | .......................................................... 59 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after confirming receipt of laboratory test) | .......................................................... 60 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Finish | .......................................................... 61 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button – Male - Confirm | .......................................................... 62 |
| Prescriber - Manage Patients – Confirm Patient Counseling Button - Male - Finish | .......................................................... 63 |
| Prescriber - Manage Patients – Edit Patient Contraception Button. Patient is in Window 1, or previous prescription window contraception selection is non-Abstinence | .......................................................... 64 |
| Prescriber - Manage Patients – Edit Patient Contraception Button. Patient’s previous prescription window contraception selection is Abstinence | .......................................................... 65 |
| Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Specimen Collection Date | .......................................................... 66 |
| Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Pregnancy Test Type | .......................................................... 67 |
| Prescriber - Manage Patients – Post-therapy Pregnancy Test Button - Enter Post-therapy Pregnancy Test Results - Finish | .......................................................... 68 |
| Prescriber - Manage Patients – Check Patient Status Button – FRP | .......................................................... 69 |
Patient Program Status Screen – More Information ........................................................................................................ 70
Prescriber - Manage Patients – Check Patient Status Button – FRP – Patient with expired Rx window ............ 71
Prescriber - Manage Patients – Check Patient Status Button – Male/FNRP .............................................................. 72
Prescriber - Manage Patients – Re-register Patient Button ......................................................................................... 73
Prescriber - Manage Patients – Re-register Patient Button – Patient linked to a different Prescriber .......... 74
Prescriber - Manage Patients – Re-register Patient Button – FRP – In-Office Pregnancy Test Results ............ 75
Prescriber - Manage Patients – Re-register Patient Button – FRP – Patient Information ............................................ 76
Prescriber - Manage Patients – Re-register Patient Button – FRP – Patient Information ................................. 77
Prescriber - Manage Patients – Re-register Patient Button – FRP – Finish ................................................................. 79
Prescriber - Manage Patients – Re-register Patient Button – FNRP ........................................................................... 80
Prescriber - Manage Patients – Re-register Patient Button – FNRP – Determine Patient Category ......... 81
Prescriber - Manage Patients – Re-register Patient Button – FNRP – Determine Patient Category – Question 1 of 3 ......................................................................................................................................................... 82
Prescriber - Manage Patients – Re-register Patient Button – FNRP – Determine Patient Category – Question 3 of 3 ......................................................................................................................................................... 84
Prescriber - Manage Patients – Re-register Patient Button – FNRP – System determines Patient Category as FRP ......................................................................................................................................................... 85
Prescriber - Manage Patients – Re-register Patient Button – Request FNRP Status ............................................. 86
Prescriber - Manage Patients – Re-register Patient Button – FNRP – Patient Information .............................. 87
Prescriber - Manage Patients – Re-register Patient Button – Request FNRP Status – Finish ......................... 90
Prescriber - Manage Patients – Re-register Patient Button – MALE .............................................................................. 91
Prescriber - Manage Patients – Re-register Patient Button – MALE – Patient Information ....................................... 92
Prescriber - Manage Patients – Re-register Patient Button – MALE – Patient Information ....................................... 93
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP ...................................................... 95
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results ................ 96
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results – Finish ...... 97
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – Negative Pregnancy Test Results ......................................................................................................................................................... 98
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – Negative PT Results – Finish 99
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP .................................................. 100
Prescriber Registration – For Prescribers (Button) from Public Home Page
Prescriber Registration – Invalid Identifiers DEA Message

Information Validation Request

Due to the launch of the enhanced iPLEDGE Program Website, please review and confirm your contact information. This is a one-time request and this message will not appear again once you have confirmed your information.

Continue

Last Name
Smith

Specialty (Optional)
Derm

Practice Name (Optional)

Address
123 Test Drive

City
Blue Bay

State
PA

Zip
18734

Preferred Method of Communication
Email

Phone Number
555551212

Email (Optional)
test@poi.com

Fax Number (Optional)

Prescriber Identifiers

This notification is to inform you that with the launch of the REIS Pharmacy Network, the iPLEDGE Program will require prescribers to provide a National Provider Identifier (NPI). If your NPI is not on file with the iPLEDGE Program, you will be prompted to enter your NPI upon first log-in to the enhanced iPLEDGE Program. Additionally, if you are registered with the Drug Enforcement Administration (DEA), the system will require entry of your DEA number. Failure to supply these identifiers may result in your patient’s prescriptions not being authorized for dispensing.

DEA
AB1234567

NPI
1234567890

I do not have a DEA

Cancel
Save Changes
Prescriber Home Page – Activated Prescriber not within 30 days of expiration.

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 isotretinoin. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, kidneys, allergic reactions, blood sugar levels, and the 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.

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.
Prescriber Home Page – Prescriber in Program Status “Registered” or activated
Prescriber whose activation expires within 30 days.

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 PLEDGE®. Under this program, prescribers must be registered and activated with the PLEDGE Program and can prescribe isotretinoin only to registered patients who meet all the requirements of PLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with PLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with PLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of harming 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 insert 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 PLEDGE Program annually. Please click the Activate button below to begin.

How to Report?

Call our toll free number 1-866-495-0054 to report any of the following:

An Adverse Event: If you or someone you know has experienced an adverse event, please call 1-866-495-0054.

A Pregnancy: To report a pregnancy, please call 1-866-495-0054.
Prescriber - Prescriber Activation

Prescriber Activation

Prescribers can only activate their registration by affirming that they meet requirements and will comply with all iPLEDGE Program 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 booklet entitled Guide to Best Practices for the iPLEDGE Program and Prescriber Contraception Counseling Guide.
- 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 methods of contraception simultaneously and continuously for at least one month prior to initiation of isotretinoin treatment, during isotretinoin treatment and for one month after discontinuing isotretinoin treatment, 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 one month later.
- I will report any pregnancy case that I become aware of while the female patient is on isotretinoin or one 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
Prescriber - Prescriber Activation - Compliance Notice

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 are routinely analyzed to identify actions of Non-Compliance.

Information entered into the iPLEDGE Program 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 Permanent Deactivation from the iPLEDGE Program. Click here to view the Non-Compliance Action Policy.

Prescribers are responsible for all iPLEDGE Program activities performed by their office staff designees. If an office staff designee is found to be non-compliant in the iPLEDGE Program, resulting actions, including possible Permanent Deactivation 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
Prescriber - 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: MM/DD/YYYY

Finish
Register New Patient

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 a Male

[Buttons: Cancel, Continue]
Register New Patient

Enter In-Office Pregnancy Test Results. All fields below are required unless otherwise indicated.

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)
Prescriber - Register New Patient – FRP

Register New Patient

Enter Patient Information for Jane Smith - continued:

All fields below are required unless otherwise indicated.

- **Phone Number**
- **Email (Optional)**
- **Date of Birth (MM/DD/YYYY)**
- **Last Four Digits of Social Security Number**
- **Preferred Method of Communication**

- **Check this box if the patient doesn’t have a social security number.**
- **I have obtained the signed program consent form(s) from the patient.**

- **Cancel**
- **Back**
- **Continue**
Prescriber - Register New Patient – FRP

Register New Patient

Patient Information Review:

Patient Name: Jane Smith
Address: 123 Test Drive, Blue Bell, PA 19754-4578
Phone Number: 555-555-1212
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(s) from the patient.

Cancel | Back | Continue
The 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.

Patient Name: Jane Smith
Address: 123 Blue Moon St, Blue Bell, PA 18754-4578
Date of Birth: 4/18/1977
Last Four Digits of Social Security Number: 1977

Please Enter Override Code
Register New Patient

Enter Patient Identification Number for Jane Smith:

All fields below are required unless otherwise indicated.

Please find the patient identification number from the patient education materials, and enter it below:

Patient Identification Number

Patient Identification Number (Type Again)

Cancel  Continue
Register New Patient

Patient Registration is complete for Jane Smith. 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 mm/dd/yyyy. The patient must be counseled to avoid pregnancy by using two methods of iPLEDGE-approved contraception simultaneously and continuously for at least one month prior to initiation of isotretinoin treatment, unless she commits to continuous abstinence.

Do not give the patient a prescription to fill until after you provide this confirmation.

Finish
Prescriber – Register New Patient - FNR

Register New Patient

Determine Patient Category:

Select Patient Category:
- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNR)
- Patient is Male

[button] Cancel  [button] Continue
Prescriber - Register New Patient – FNRP – Acknowledgement

Register New Patient

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
- Male Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopause)

Please acknowledge your understanding of the qualification criteria as presented to proceed with assigning a risk category to this patient.

[Cancel] [I Acknowledge]
**Prescriber - Register New Patient – FNRP – Determine Patient Category**

Question 1 of 3

### Register New Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUE #</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Determine Patient Category:

Has patient had a hysterectomy?

- Yes
- No

---

**Notice!**

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

---

[iPLEDGE Terms of Use] | [Safety Notice] | [Non-Compliance Action Policy] | © 2018 iPLEDGE
Prescriber - Register New Patient – FNR P – Determine Patient Category
Question 2 of 3

Register New Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUE #</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Determine Patient Category:

Has patient had a bi-lateral oophorectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your patient's classification. Intentional falsification of patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel  Continue
Prescriber - Register New Patient – FNRP – Determine Patient Category
Question 3 of 3

Register New Patient

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 you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

[Buttons: Cancel, Continue]
Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FNRP

### Register New Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

**Review Patient Category:**

Based on your responses the iPLEDGE Program system has categorized this patient as follows:

- **Patient is a Female of NON-Reproductive Potential (FNRP)**

Based on the following criteria:

- **Is patient a 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 you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

[Back] [Continue]
Register New Patient

Enter Patient Identification Number for Jane Smith:

All fields below are required unless otherwise indicated.

Please find the patient identification number from the patient education materials, and enter it below.

- Patient Identification Number
- Patient Identification Number (Type Again)

Cancel  Continue
Patient Registration is complete for Jane Smith. A password will be mailed to the patient, and should be received within 5 to 10 days.

Before Jane Smith's can fill a prescription, you must confirm patient counseling in the system. Please click the Continue button below to start the confirmation process.

Otherwise select the Finish button to complete Jane Smith's registration. Note: you may confirm Jane Smith at a later date using the Manage Patients screen.
Prescriber - Register New Patient – FNRP – Continue option to confirm FNRP

Confirm Patient Counseling

Identification Number: 3306061966
First Name: Jane
Last Name: Smith
Date of Birth: 06/06/1996

- I have counseled this patient on the following:
  - Isotretinoin 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.

In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.
- Yes
- No

Selecting the Continue button confirms that you have provided the monthly counseling to this patient.
Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Identification Number: 3365651986
First Name: Jane
Last Name: Smith
Date of Birth: 06/06/1966

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 mm/dd/yyyy.

Finish
Prescriber - Register New Patient – FNRP – Review Patient Category – System determines patient is FRP

Register New Patient

Category | Review | Pregnancy Result | Patient Info | Uniqueness | Identification | Finish
---|---|---|---|---|---|---

Review Patient Category:

Based on your responses the iPLEDGE Program system has categorized this patient as follows:
Patient is a Female of Reproductive Potential (FRP)

Based on the following criteria:
- Is patient a Male? No
- Has patient had a hysterectomy? No
- Has patient had a bilateral 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
### Register New Patient

#### 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
- Male 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.
Prescriber - Register New Patient – MALE

Register New Patient

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 a Male

Notice!
Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel    Continue
Prescriber - Register New Patient – MALE – Patient Information

### Register New Patient

Enter Patient Information:

All fields below are required unless otherwise indicated.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Required</td>
</tr>
<tr>
<td>Last Name</td>
<td>Optional</td>
</tr>
<tr>
<td>Address</td>
<td>Optional</td>
</tr>
<tr>
<td>City</td>
<td>Optional</td>
</tr>
<tr>
<td>State</td>
<td>Optional</td>
</tr>
<tr>
<td>Zip</td>
<td>Optional</td>
</tr>
</tbody>
</table>

### Actions

- **Cancel**
- **Continue**
Prescriber - Register New Patient – MALE – Patient Information Review

Register New Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Patient Information Review:

Patient Name: John Smith
Address: 123 Test Drive, Blue Bell, PA 18754.4578
Phone Number: 555-555-1212
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.

Cancel  Back  Continue

Register New Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION#</th>
<th>FINISH</th>
</tr>
</thead>
</table>

The patient may not be unique.

Please contact the Call Center at 1-866-495-9654 to obtain an override code.

You may need the patient information below to assist the Call Center Representative in determining patient uniqueness.

Patient Name: John Smith
Address: 123 Blue Moon St, Blue Bell, PA 18754-4578
Date of Birth: 4/18/1977
Last Four Digits of Social Security Number: 1977

Please Enter Override Code

Cancel  Continue
Prescriber - Register New Patient – MALE – Identification Number Entry

Enter Patient Identification Number for John Smith:

All fields below are required unless otherwise indicated.

Please find the patient identification number from the patient education materials, and enter it below.

Patient Identification Number

Patient Identification Number (Type Again)

Cancel  Continue
Patient Registration is complete for John Smith’s.
A password will be mailed to the patient, and should be received within 5 to 10 days.

Before John Smith’s can fill a prescription, you must confirm patient counseling in the system. Please click the Continue button below to start the confirmation process.

Notice!
Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Otherwise select the Finish button to complete John Smith’s registration.
Note: You may confirm John Smith at a later date using the Manage Patients screen.

Finish
Prescriber - Register New Patient – MALE – Continue to Confirm after Finish

Confirm Patient Counseling

Identification Number: 3367071977
First Name: John
Last Name: Smith
Date of Birth: 07/07/1977

- I have counseled this patient on the following:
  - Isotretinoin 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.

In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.

- Yes
- No

Selecting the "Continue" button confirms that you have provided the monthly counseling to this patient.

Cancel     Continue
Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Identification Number: 3307071977
First Name: John
Last Name: Smith
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 m/dd/yyyy.

Finish
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, microtia, small or absent external auditory canals); eye abnormalities (including microphthalmia), facial dysmorphism, 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 iPledge, and must only be dispensed to patients who are registered and meet all the requirements of 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 reproductive 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 Program 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 reproductive potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of reproductive potential selects and commits to use two methods 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.

Each month, the prescriber must enter the female patient’s pregnancy results and the 2 methods of contraception she has been using in the iPLEDGE Program system. The iPLEDGE Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPLEDGE Program system via the internet (www.ipledgeprogram.com), telephone (1-866-495-0654) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.
Prescriber - Manage Patients
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

Cancel  Continue
Prescriber - Manage Patients – Request Exemption Option Selected

Exemption for Female Patients With Serious Medical Reasons

Notice!
The intention of this form is to request an exemption from the iPLEDGE requirements for a non-pregnant patient with serious medical reasons(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 the 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

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
Prescriber - Manage Patients – Report Tanner Stage Change button

Tanner Stage 1 or 2 Classification Change Notification

This patient 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
Prescriber - Manage Patients – Status Column – Red info button - SAMPLE

**Program Status Descriptions by Patient Type**

**Females 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 methods of effective contraception before she can start the qualification process for a prescription.

or

This patient did not obtain 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 the iFLEDGE Program, but will now be using two other methods of contraception. This patient must be on the new methods 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-reproductive potential, but is still waiting for entry of an initial pregnancy test.

or

A patient that was determined to be a female of reproductive potential during the registration process, but there is a pending request to assign a risk category of female of non-reproductive 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 obtain 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 obtained 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-reproductive potential status, this patient cannot be confirmed until the request is reviewed and accepted through discussion with the iFLEDGE Program Call Center.
Prescriber - Manage Patients – Edit Patient Demographics Button

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.

All fields below are required unless otherwise indicated.

First Name: Jane
Last Name: Smith
Address: 123 Blue Moon St.
City: Blue Bell
State: PA
Zip: 19854
Phone Number: 555-555-1212
Date of Birth (MM/DD/YYYY): 04/18/1997

[Buttons: Cancel, Save Changes]
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Confirm

Confirm Patient Counseling

- Identification Number: 3306061966
- First Name: Jane
- Last Name: Smith
- Date of Birth: 06/06/1996

- I have obtained the signed program consent form(s) from the patient.
- I have counseled this patient on the following:
  - Requirement to use two methods of contraception simultaneously and continuously for at least one month prior to initiation of isotretinoin treatment, during isotretinoin treatment and for one month after discontinuing isotretinoin treatment, unless the patient commits to continuous abstinence.
  - Isotretinoin 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.

In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program:

- Yes
- No

Selecting the Continue button confirms that you have provided the monthly counseling to this patient.
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Contraception

Confirm Patient Counseling

Identification Number: 370391967
First Name: Jane
Last Name: Smith
Date of Birth: 03/09/1967

Please enter the methods of contraception:

Primary:

Secondary:

- I have provided Contraception Counseling to this patient
  Date Contraception Counseling was provided:

- This patient was referred to and obtained Contraception Counseling from another Health Care Provider
  Date Contraception Counseling was provided:

[Options for selecting contraception methods]

[Buttons: Cancel, Back, Continue]
A secondary method will not be allowed to be entered if abstinence is selected as the primary method.
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Did not fill Rx in previous window – Message

Confirm Patient Counseling

Identification Number: 3703091967
First Name: Jane
Last Name: Smith
Date of Birth: 03/09/1967

More Information

IPLEDEGE has no record of this patient filling a prescription in their previous prescription window. Did this patient fill their prescription during this previous prescription window?

- Yes
- No
- I do not know

Submit

Cancel
Confirm Patient Counseling

Identification Number: 3703091967
First Name: Jane
Last Name: Smith
Date of Birth: 03/09/1967

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.
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after closing of popup message)
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP – Pregnancy Result (after confirming receipt of laboratory test)

Confirm Patient Counseling

Identification Number: 3304181997
First Name: Jane
Last Name: Smith
Date of Birth: 04/19/1997

Pregnancy Test Specimen collected on: [ ] [ ] [ ]

Pregnancy Test Type: [ ] Quantitative Serum
[ ] Qualitative Serum
[ ] Urine

Lab Test Results: [ ] Positive
[ ] Negative

Prescriber Diagnosis: [ ] Pregnant
[ ] Not Pregnant

[ ] Cancel  [ ] Back  [ ] Continue
Prescriber - Manage Patients – Confirm Patient Counseling Button – FRP - Finish

Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

| Identification Number: 3304181997 |
| First Name: Jane |
| Last Name: Smith |
| Date of Birth: 04/10/1997 |

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
Confirms Patient Counseling

- Identification Number: 3304041914
- First Name: John
- Last Name: Smith
- Date of Birth: 04/04/1914

- I have counseled this patient on the following:
  - Isotretinoin 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.

In my opinion, this patient understands and is capable of complying with the requirements of the iPLEDGE Program.
- Yes
- No

Selecting the Continue button confirms that you have provided the monthly counseling to this patient.
Confirm Patient Counseling

- Confirm Patient Counseling is Complete.

Identification Number: 3307071977
First Name: John
Last Name: Smith
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 mm/dd/yyyy.

Finish
Prescriber - Manage Patients – Edit Patient Contraception Button. Patient is in Window 1, or previous prescription window contraception selection is non-Abstinence.
Prescriber - Manage Patients – Edit Patient Contraception Button. Patient’s previous prescription window contraception selection is Abstinence.

Change Contraception Choices

Identification Number: 3703691967
First Name: John
Last Name: Smith
Date of Birth: 03/09/1967
Current Program Status: Required to Demonstrate Comprehension

Current contraception methods:

Primary:
Abstinence
Secondary:
None

Please enter patient’s new contraception methods. All fields below are required unless otherwise indicated.

Primary:
Birth Control Pills ▼
Secondary:
Male Latex Condom ▼

☐ I understand that switching from Abstinence requires a 30 day waiting period.

Cancel  Save Changes
Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Specimen Collection Date

Enter Post-therapy Pregnancy Test Results

- Identification Number: 30111101931
- First Name: Jenna
- Last Name: Jones
- Date of Birth: 11/10/1991
- Current Program Status: Permanently Lost to Follow Up

Enter the Specimen Collection Date:
- Jun
- /
- /

[Cancel] [Continue]
Prescriber - Manage Patients – Post-therapy Pregnancy Test Button – Pregnancy Test Type
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 7/12/2015.

Finish
Prescriber - Manage Patients – Check Patient Status Button – FRP

Patient Program Status as of 6/1/2015 2:44 PM Eastern Time

Name: Jane Smith

Program Status: Required to Demonstrate Comprehension

Action: No prescriber action is required at this time.

Information: Before the patient can obtain 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

<table>
<thead>
<tr>
<th>Sun</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Key**

- Today or future day for an active 7 day window
- A 7 day window that has expired without prescription fill
- A past day for a 7 day window
- Action may occur on this date or any date after

You may click on [underlined text](#) to perform the required action.
Patient Program Status Screen – 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 Program system. The results of the pregnancy test will be entered in the iPLEDGE Program system by the prescriber as part of the confirmation.

Confirmation, including entering the results of the pregnancy test and confirming patient counseling in the iPLEDGE Program 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 iPLEDGE Program 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 iPLEDGE Program 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’s Program Status page.

Once the prescriber has entered the pregnancy test results and has confirmed counseling in the iPLEDGE Program system, this calendar will show the 7-day prescription window.
Prescriber - Manage Patients – Check Patient Status Button – FRP – Patient with expired Rx window

Patient Program Status as of 6/1/2015 3:46 PM Eastern Time

Name: Jenna Jones
Program Status: Registered
Action: No prescriber action is required at this time.

Information: This 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

<table>
<thead>
<tr>
<th>Sun</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
</tr>
</thead>
<tbody>
<tr>
<td>24</td>
<td>25</td>
<td>26</td>
<td>27</td>
<td>28</td>
<td>29</td>
<td>30</td>
</tr>
</tbody>
</table>

- Patient may answer their questions More.
- Patient may answer their questions More.
- Patient may answer their questions More.
- Patient may answer their questions More.
- Patient may answer their questions More.
- Patient may answer their questions More.

Last day patient may answer their questions More.
First day of required lock out More.

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.
Patient Program Status as of 6/1/2015 3:59 PM Eastern Time

Name: Jane Smith
Program Status: Qualified to Receive Drug
Action: No prescriber action is required at this time.
Expense Date: 6/30/2015 11:59:59 PM

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.
Prescriber - Manage Patients – Re-register Patient Button

Re-register Patient

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

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel  Continue
Prescriber - Manage Patients – Re-register Patient Button – Patient linked to a different Prescriber

Re-register Patient

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 a Male

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your patient's classification. Intentional falsification of patient classification type will result in Permanent Deactivation from the IPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Continue

Cancel
Prescriber - Manage Patients – Re-register Patient Button – FRP – In-Office Pregnancy Test Results

Re-register Patient

Enter In-Office Pregnancy Test Results:

All fields below are required unless otherwise indicated.

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)

Cancel Continue
Re-register Patient

Enter Patient Information:

All fields below are required unless otherwise indicated.

First Name: Jenna
Last Name: Jones
Address: 421 Seabrook Road
City: Blue Bell
State: PA
Zip: 19854
Prescriber - Manage Patients – Re-register Patient Button – FRP – Patient Information

Re-register Patient

Enter Patient Information for Jenna Jones - continued:

<table>
<thead>
<tr>
<th>Category</th>
<th>Review</th>
<th>Pregnancy Result</th>
<th>Patient Info</th>
<th>Uniqueness</th>
<th>Identification #</th>
<th>Finish</th>
</tr>
</thead>
</table>

All fields below are required unless otherwise indicated.

Phone Number: 2155221212

Email (Optional): jennaj@email.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(s) from the patient.

Cancel  Back  Continue

Re-register Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Patient Information Review:

- Patient Name: Jenna Jones
- Address: 421 Seabrook Road, Blue Bell, PA 19854
- Phone Number: 215-522-1212
- Email: jenmai@email.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(s) from the patient.

[Buttons: Cancel, Back, Continue]
### Re-register Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

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**
 Prescriber - Manage Patients – Re-register Patient Button – FNR

<table>
<thead>
<tr>
<th>Re-register Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category</strong></td>
</tr>
</tbody>
</table>

Determine Patient Category

Select Patient Category

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNR)
- Patient is a Male

**Notice!**

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the IPLEdge Program and a permanent loss of isotretinoin prescribing privileges.

[Cancel] [Continue]
Prescriber - Manage Patients – Re-register Patient Button – FNRP – Determine Patient Category

Re-register Patient

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
  - Male 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.

  - [ ] Cancel
  - I Acknowledge

[iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2016 iPLEDGE]

Re-register Patient

---

Determine Patient Category:

Has patient had a hysterectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanet Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

- Cancel
- Continue

Re-register Patient

Determine Patient Category:

Has patient had a bilateral oophorectomy?

- Yes
- No

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient’s classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel  Continue
Re-register Patient

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 assays 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 you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.
Prescriber - Manage Patients – Re-register Patient Button – FNRP – System determines Patient Category as FRP

Re-register Patient

Review Patient Category:

Based on your responses the iPLEDGE Program system has categorized this patient as follows:

Patient is a Female of Reproductive Potential (FRP)

Based on the following criteria:

- Is patient a Male? Yes
- Has patient had a hysterectomy? No
- Has patient had a bilateral 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
Prescriber - Manage Patients – Re-register Patient Button – Request FNRP Status

Re-register Patient

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
- Male Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopause)

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.
Prescriber - Manage Patients – Re-register Patient Button – FNR/P – Patient Information

Re-register Patient

Enter Patient Information for John Smith - continued:

All fields below are required unless otherwise indicated.

Phone Number: 1231231231
Email (Optional): email@email.com
Date of Birth (MM/DD/YYYY): 02/03/1968
Last Four Digits of Social Security Number: 1968

Preferred Method of Communication:
U.S. Mail

I have obtained the signed program consent form from the patient.
Re-register Patient

Patient Information Review:

<table>
<thead>
<tr>
<th>Category</th>
<th>Review</th>
<th>Pregnancy Result</th>
<th>Patient Info</th>
<th>Uniqueness</th>
<th>Identification</th>
<th>Finish</th>
</tr>
</thead>
</table>

- Patient Name: John Smith
- Address: 123 Test Testing, PW 12345
- Phone Number: 123-123-1231
- Email: email@email.com
- 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.
Prescriber - Manage Patients – Re-register Patient Button – Request FNRP Status – Finish

Re-register Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Patient Jane Smith
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 registered 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 to complete this portion of the patient's registration.

Finish
Re-register Patient

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 a Male

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel  Continue
Prescriber - Manage Patients – Re-register Patient Button – MALE – Patient Information

### Re-register Patient

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>PATIENT INFO</th>
<th>UNIQUENESS</th>
<th>IDENTIFICATION #</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Enter Patient Information:

All fields below are required unless otherwise indicated.

- **First Name**: John
- **Last Name**: Smith
- **Address**: 123 Test St.
- **City**: Testing
- **State**: PA
- **Zip**: 12345

[Cancel] [Continue]
Re-register Patient

Patient Information Review:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>John Smith</td>
</tr>
<tr>
<td>Address</td>
<td>123 Test Testing, PW 12345</td>
</tr>
<tr>
<td>Phone Number</td>
<td>123-123-1231</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:email@email.com">email@email.com</a></td>
</tr>
<tr>
<td>Preferred Method of Communication</td>
<td>U.S. Mail</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>8/20/1968</td>
</tr>
<tr>
<td>Last Four Digits of Social Security Number</td>
<td>1968</td>
</tr>
</tbody>
</table>

I have obtained the signed program consent form from the patient.
Re-register Patient

Patient Registration is complete for John Smith. Patient may use their current Patient ID and Password.

Before John Smith can fill a prescription, you must confirm patient counseling in the system. Please click the Continue button below to start the confirmation process.

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Otherwise select the Finish button to complete John Smith's registration. Note: You may confirm John Smith's at a later date using the Manage Patients screen.

Continue

Finish
### Change Patient Type

**Determine Patient Category:**

Select Patient Category:

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)

<table>
<thead>
<tr>
<th>Category</th>
<th>Review</th>
<th>Pregnancy Result</th>
<th>Finish</th>
</tr>
</thead>
</table>

[Cancel] [Continue]
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results

Change Patient Type

Enter In-Office Pregnancy Test Results. All fields below are required unless otherwise indicated.

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)

[Buttons: Cancel, Continue]
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – No PT Results – Finish

Change Patient Type

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>FINISH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Patient Name: Jane Smith
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 methods of contraception.

Finish
Prescriber - Manage Patients – Change Patient Type Button – Change to FRP – Negative Pregnancy Test Results

Change Patient Type

Enter In-Office Pregnancy Test Results. All fields below are required unless otherwise indicated.

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)

[Buttons: Cancel, Continue]
### Change Patient Type

<table>
<thead>
<tr>
<th>Category</th>
<th>Review</th>
<th>Pregnancy Result</th>
<th>Finish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>Jane Smith</td>
<td>Female of Reproductive Potential (FRP)</td>
<td></td>
</tr>
<tr>
<td>Patient Type has been changed to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Status has been changed to</td>
<td>Registered</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 methods 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 methods of contraception for 1 month.

Finish
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRPP

---

**Change Patient Type**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>FINISH</th>
</tr>
</thead>
</table>

**Determine Patient Category**

**Select Patient Category**

- Patient is a Female of Reproductive Potential (FRP)
- Patient is a Female NOT of Reproductive Potential (FNRP)

---

**Cancel**  **Continue**
Prescriber - Manage Patients – Change Patient Type Button – Change to FNR – Determine Patient Category

Change Patient Type

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
- Male Vasectomy
- Abstinence
- Patient has not had her first period (pre-menarche)
- Patient is currently in menopause (but not yet post-menopause)

Please acknowledge your understanding of the qualification criteria as presented to proceed with assigning a risk category to this patient.
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Question 1 of 3

Change Patient Type

Determine Patient Category:

- Has patient had a hysterectomy?
  - Yes
  - No

Notice!

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

Cancel  Continue
Determine Patient Category:

Has patient had a bi-lateral oophorectomy?

- Yes
- No

**Notice!**

Make sure that you are correctly classifying your patient as you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.

[Cancel] [Continue]
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRAP – Determine Patient Category – Question 3 of 3

### Change Patient Type

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>FINISH</th>
</tr>
</thead>
</table>

**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 you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Review

**Change Patient Type**

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Review Patient Category:

Based on your responses the iPLEDGE Program 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 bilateral 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]
### Change Patient Type

#### Review Patient Category:

Based on your responses the iPLEDGE Program system has categorized this patient as follows:

**Patient is a Female of NON-Reproductive Potential (FNRP)**

Based on the following criteria:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is patient a Male?</td>
<td>No</td>
</tr>
<tr>
<td>Has patient had a hysterectomy?</td>
<td>Yes</td>
</tr>
<tr>
<td>Has patient had a bi-lateral oophorectomy?</td>
<td>Yes</td>
</tr>
<tr>
<td>Is this patient post-menopausal?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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 you may be required to provide documentation to support your Patient's classification. Intentional falsification of Patient classification type will result in Permanent Deactivation from the iPLEDGE Program and a permanent loss of isotretinoin prescribing privileges.
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Request FNRP

Change Patient Type

Review Patient Category:

Notice!
Your responses indicate that the 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
- Male 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 1-866-485-0654 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
Prescriber - Manage Patients – Change Patient Type Button – Change to FNRP – Determine Patient Category – Request FNRP – Finish

Change Patient Type

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>REVIEW</th>
<th>PREGNANCY RESULT</th>
<th>FINISH</th>
</tr>
</thead>
</table>

Patient Jane Smith.
Patient may use their current Patient ID and Password.

Registration is not complete until the request for FNRP status is approved by the iPLEDGE Program. This patient will not be able to start therapy until approved as a FNRP or until you register the patient as a PRP.

Please contact the Call Center at 1-855-495-0654 to provide further information. You may be required to provide documentation to support this request.

Select the Finish button to complete this portion of the patient’s registration.

Finish
Prescriber - Manage Patients – Discontinue Patient Button – Discontinue Reasons

Discontinue Patient

All fields below are required unless otherwise indicated.

Patient ID: 3911101993
First Name: Jane
Last Name: Smith
Date of Birth: 11/10/1993

The iPLEDGE Program 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?

- Yes
- No
- Not Sure

Discontinue Reason:
- Patient Completed Therapy
- Patient is Lost to Follow Up
- Pregnancy
- Patient has Insurance Considerations
- Patient Never Started Therapy
- Other

Cancel Continue
Report Pregnancy

Identification Number: 3304181997
First Name: Jane
Last Name: Smith
Date of Birth: 04/18/1997
Current Program Status: Registered

Enter the Specimen Collection Date:
May 28 / 2015

Cancel Continue
Prescriber - Manage Patients – Report Pregnancy Button

Report Pregnancy

Identification Number: 3304181997
First Name: Jane
Last Name: Smith
Date of Birth: 04/18/1997
Current Program Status: Registered

Confirm the Specimen Collection Date:
Specimen Collection Date you entered is: 5/20/2015

☐ 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]
Prescriber - Manage Patients – Report Pregnancy Button – Confirmation

Report Pregnancy

Identification Number: 3911101993
First Name: Jane
Last Name: Smith
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.

Back  Confirm
Prescriber – Prescriber Information

Prescriber Information

About Prescriber Information
The goals of the PLEDGE 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:
- Patient Introduction Brochure
- Guide to Best Practices For The PLEDGE Program
- Prescriber Contraception Counseling Guide
- Recognizing Psychiatric Disorders in Adolescents and Young Adults: A Guide for Prescribers of Isotretinoin
- Isotretinoin Information: Informed Consent About Birth Defects (for female patients who can get pregnant)
- Isotretinoin Information: Informed Consent (for all patients)
- Prescriber Checklist for Male Patients of Childbearing Potential
- Prescriber Checklist for Male Patients and Female Patients Who Cannot Get Pregnant
- Prescriber Toolkit
- Prescriber Activation Instructions
- Instructions for Registering and Managing Office Staff Designees

Lessons Learned:
- About Lifesaver Medication
- About Birth Control
- About Post-Treatment Pregnancy Testing

Package Inserts:
- Dr. Reddy’s Zan cognatis Package Insert
- Mylan Amnioncin Package Insert
- Ranbaxy Abscess Package Insert
- Ranbaxy Retin-A Package Insert
- Taro Cialis Package Insert
- Versapharm Mycologis Package Insert

Patient Information:
- Guide to Isotretinoin for Female Patients Who Can Get Pregnant
- Birth Control Worksheet
- PLEDGE Program Birth Control Information Sheet
- PLEDGE Program Checklist
- Contraception Counseling Guide and Contraception Referral Form
- Isotretinoin Contraception Referral Form
- Guide to Isotretinoin for Male Patients and Female Patients Who Cannot Get Pregnant
- Safety Information About Isotretinoin

Medication Guides:
- Dr. Reddy’s Zan cognatis Medication Guide
- Mylan Amnioncin Medication Guide
- Ranbaxy Abscess Medication Guide
- Ranbaxy Retin-A Medication Guide
- Taro Cialis Medication Guide
- Versapharm Mycologis Medication Guide

Manufacturers’ Toll-free Numbers
For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnioncin®</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1-800-766-3526</td>
</tr>
<tr>
<td>Claravis™</td>
<td>Teva Pharmaceuticals USA</td>
<td>1-800-227-7322</td>
</tr>
<tr>
<td>Solbet®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-466-7984</td>
</tr>
<tr>
<td>Mycologis®</td>
<td>Versapharm Incorporated</td>
<td>1-877-254-4381</td>
</tr>
<tr>
<td>Abscess®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1-800-466-7984</td>
</tr>
<tr>
<td>Zan cognatis®</td>
<td>Dr. Reddy’s Laboratories, Ltd.</td>
<td>1-888-375-3764</td>
</tr>
</tbody>
</table>
Prescriber - Order Materials

Order Materials

Enter quantities you would like to order

- PLEDGE Program Birth Control Information Sheet/PLEDGE Program Checklist (1 to 10 sheets)
- Prescribing checklist for Female Patients of Reproductive Potential (1 to 3 pads of 50 tear sheets)
- Prescribing checklist for Male Patients and Female Patients of Non-Reproductive Potential (1 to 3 pads of 50 tear sheets)
- Educational DVDs: Be Prepared, Be Protected and Be Aware: The Risk of Pregnancy while on Isotretinoin (1 DVD)
- Patient Introductory Brochure (1 to 3 packages of 5)
- Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant (1 to 10 kits)
- Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant (1 to 10 kits)
- Prescriber Isotretinoin Educational Kit (1 Kit)
- Spanish Patient Introductory Brochure (1 to 3 packages of 5)
- Spanish Isotretinoin Educational Kit for Female Patients Who Can Get Pregnant (1 to 10 kits)
- Spanish Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant (1 to 10 kits)

Place Order
Prescriber - Update My Information

Update My Information

- Change Password
- Change Date of Personal Significance
- Edit Prescriber Demographics

HOME
PRESCRIBER ACTIVATION
REGISTER NEW PATIENT
ABOUT ISORETINOIN
ABOUT IPLUGGE
MANAGE PATIENTS
PRESCRIBER INFORMATION
ORDER MATERIALS
UPDATE MY INFORMATION
ACCEPT PATIENT
MANAGE DELEGATES/DESIIGNEES
MY PROGRAM STATUS
FIND A PARTICIPATING PHARMACY
FAQS
ACTION REQUIRED LIST

iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2016 iPLEDGE

Have Questions? Call our toll-free number 1-888-495-0854
Prescriber - Update My Information – Change Password

Change Password

All fields below are required unless otherwise indicated.

Old Password

New Password

Confirm New Password

Save Changes
# 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. All fields below are required unless otherwise indicated:

- **Password:**
- **Date of Personal Significance:** (MM/DD/YYYY)
- **Confirm Date of Personal Significance:** (MM/DD/YYYY)

[Save Changes]
Prescriber - Update My Information – Contact Info

Update Contact Information

Use this form to edit your contact information. Enter or confirm your information. All fields below are required unless otherwise indicated.

First Name

MI (Optional) Suffix (Optional)

Last Name

Specialty (Optional)

Practos Name (Optional)

Address

City

State Zip

Preferred Method of Communication

Phone Number Ext (Optional)

Email (Optional)

Fax Number (Optional)

Prescriber Identifiers

This notification is to inform you that with the launch of the REMS Pharmacy Network, the iPLEDGE Program will require prescribers to provide a National Provider Identifier (NPI). If your NPI is not on file with the iPLEDGE Program, you will be prompted to enter your NPI upon first log-in to the enhanced iPLEDGE Program. Additionally, if you are registered with the Drug Enforcement Administration (DEA), the system will require entry of your DEA number. **Failure to supply those identifiers may result in your patients’ prescriptions not being authorized for dispensing.**

DEA

NPI

☐ I do not have a DEA

Save Changes
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
Manage Delegates and Designees

Delegates

A prescriber can delegate another registered and activated iPLEDGE Program 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.

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 Program system, neither the prescriber nor the designated office staff can register a patient. The registered prescriber is responsible for all information entered and activities performed in the iPLEDGE Program by all designees under his/her supervision.
Prescriber - Manage Delegates

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

All fields below are required unless otherwise indicated.

Delegate Prescriber Username

Expiration Date (MM/DD/YYYY) (e.temporary delegate)

Add  Remove  Update
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.

Note: The registered prescriber is responsible for all information entered and activities performed in the iPLEDGE Program by all designees under his/her supervision.

All fields below are required unless otherwise indicated.

First Name

MI (Optional)

Last Name

Address

City

State

Zip

Select

Phone Number

Fax (Optional)

Email (Optional)

Preferred Method of Communication

Select

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.
Manage Designees

Designees are office staff that are registered in the iPLEDGE Program that you allow to manage your patients.

Note: The registered prescriber is responsible for all information entered and activities performed in the iPLEDGE Program by all designees under his/her supervision.

Your designees

- iPLEDGE designee
- Designee iPLEDGE
- iPLEDGE Designee
- SARAH Borkowsky

All fields below are required unless otherwise indicated.

Designee Username

- 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.
### Prescriber Program Status

**Your Program Status:** Attested

**Program Status expiration date:** 5/28/2016

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Phone</th>
<th>Date of Birth</th>
<th>Type</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRP, Female</td>
<td>123-123-1231</td>
<td>10/20/1970</td>
<td>FRP</td>
<td>Active</td>
</tr>
<tr>
<td>gtest1, Test2</td>
<td>222-222-2222</td>
<td>08/29/1999</td>
<td>FRP</td>
<td>Active</td>
</tr>
<tr>
<td>Jones, Jenna</td>
<td>215-522-1212</td>
<td>03/07/2000</td>
<td>FRP</td>
<td>Active</td>
</tr>
<tr>
<td>jseyj1, test1</td>
<td>999-999-9999</td>
<td>01/01/1940</td>
<td>FRP</td>
<td>Permanently Lost to Follow Up</td>
</tr>
<tr>
<td>Patient, FRP</td>
<td>123-123-1231</td>
<td>10/21/1921</td>
<td>FRP</td>
<td>Permanently Lost to Follow Up</td>
</tr>
<tr>
<td>Patient, FRP</td>
<td>555-555-1212</td>
<td>11/10/1991</td>
<td>FRP</td>
<td>Permanently Lost to Follow Up</td>
</tr>
<tr>
<td>Patient, FRP</td>
<td>555-555-1212</td>
<td>11/10/1993</td>
<td>FRP</td>
<td>Permanently Lost to Follow Up</td>
</tr>
<tr>
<td>patient, Male</td>
<td>123-123-1231</td>
<td>09/28/1968</td>
<td>FRP</td>
<td>Inactive</td>
</tr>
</tbody>
</table>

Showing 1 to 8 of 8 entries
Prescriber – FAQs/How To’s

Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)

A. TECHNICAL ASSISTANCE
B. PRESCRIBER
C. ALL USERS

iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2010 iPLEDGE
Prescriber – Action Required List

<table>
<thead>
<tr>
<th>Name</th>
<th>Message</th>
<th>Take Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown, Cindy</td>
<td>Enter the initial post-therapy Pregnancy Test Results, due upon completion of therapy.</td>
<td>Take Action</td>
</tr>
<tr>
<td>Brown, Sandy</td>
<td>One or both post-therapy Pregnancy Test Results are 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.</td>
<td>Take Action</td>
</tr>
<tr>
<td>Dough, Jane</td>
<td>Patient has been in “Registered” status for over 60 days. If no activity occurs, the system will discontinue this patient on 01/31/2015.</td>
<td>Take Action</td>
</tr>
<tr>
<td>Patient, FRP</td>
<td>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.</td>
<td>Take Action</td>
</tr>
<tr>
<td>Patient, Test</td>
<td>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.</td>
<td>Take Action</td>
</tr>
</tbody>
</table>

Showing 1 to 5 of 5 entries
Prescriber – 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 Pharmacist who have signed up to participate in the iPLEDGE Program. "Patients" are patients who have been prescribed restricted distribution drugs pursuant to the iPLEDGE Program. "Prescribers" are physicians that prescribe restricted distribution drugs pursuant to the iPLEDGE Program. "Designated Agents" are persons designated by Prescribers to act on their behalf with the iPLEDGE Website. Pharmacists are pharmacists that utilize the iPLEDGE Website to verify a patient's enrollment in iPLEDGE and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site ("you" or "your") and the sponsors of the Site ("iPLEDGE" "we", "us" and "our").

REGISTRATION AND ASSENT

Access to and use of the Site is conditioned upon your assent to these Terms of Use. You are deemed to have assented to these Terms of Use when you use any available page of the Site. You are deemed to have assented to these Terms of Use as applicable to the iPLEDGE Website when you complete the online registration process required for Registered Users and indicate during the registration process that you accept these Terms of Use along with the Privacy Policy incorporated therein. You are deemed to have accepted these Terms of Use each time you access the Site and each time you use your login credentials to access the iPLEDGE Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these Terms of Use. These Terms of Use and the Privacy Policy are available during registration for the iPLEDGE Website and on various pages of the Site.

UPDATES

iPLEDGE may update these Terms of Use at any time. You should therefore review these Terms of Use from time to time. Any changes made to these Terms of Use will be effective immediately upon posting to the Site. These Terms of Use and the Privacy Policy include any and all agreements between you and iPLEDGE.

iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | © 2016 iPLEDGE
Prescriber – 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 harming 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.
FDA REMS Submission

Public and Common Screens Inventory

iPLEDGE Program

Revised: December 2016
Public and Common Screens Inventory:

Table of Contents

Public Home Page ............................................................................................................. 3
Program Update Box ......................................................................................................... 4
Office Staff Designee Registration .................................................................................... 5
Common – Patient Information ......................................................................................... 6
Common – About Isotretinoin .......................................................................................... 7
Common – About iPLEDGE ............................................................................................... 8
Public – Prescriber Information ....................................................................................... 9
Public – Find a Participating Pharmacy ........................................................................... 10
Public – FAQs .................................................................................................................. 11
Common – iPLEDGE Terms of Use ................................................................................ 12
Common – Safety Notice ................................................................................................. 13
Public – Forgot Password ............................................................................................... 14
User login timed out ....................................................................................................... 15
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 isotretinoin. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lips, 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.

Registration

Patient Information  >  Pharmacy Registration  >  Prescriber Registration  >  Office Staff Designee Information  >

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 a registered prescriber, report pregnancy results by logging in and clicking on “Manage Patients.” Otherwise, please call 1-866-495-0654.
Office Staff Designee Registration

Office Staff Designee cannot register directly in the iPLEDGE Program.

All Designees must be registered in the iPLEDGE Program 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.
Common – Patient Information

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 those PDF files, you will need Adobe® Reader®.

Patient Information:
- The iPLEDGE Program Patient Introductory Brochure
- Dr. Reddy's Zetane Medication Guide
- Mylan Amnesteem Medication Guide
- Ranbaxy Absorica Medication Guide
- Ranbaxy Soriatane Medication Guide
- Teva Claravis Medication Guide
- VersaPharm Myorisan Medication Guide

Manufacturer's Toll-free Numbers

For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnesteem®</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1.800.796.9526</td>
</tr>
<tr>
<td>Claravis®</td>
<td>Teva Pharmaceuticals USA.</td>
<td>1.800.227.7522</td>
</tr>
<tr>
<td>Soriatane™</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1.800.406.7984</td>
</tr>
<tr>
<td>Zetane®</td>
<td>Dr. Reddy's Laboratories, Ltd.</td>
<td>1.888.375.3784</td>
</tr>
</tbody>
</table>
Common – About Isotretinoin

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, microtia, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphia; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebrovascular abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve defects); 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 iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.
Common – About iPLEDGE

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, distributors, 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 dispensing of the isotretinoin prescription to the female patient of reproductive 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 Program 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 reproductive potential.

As part of the ongoing risk management of isotretinoin products, it is crucial that a female of reproductive potential selects and commits to use two methods 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.

Each month, the prescriber must enter the female patient's pregnancy results and the 2 methods of contraception she has been using in the iPLEDGE Program system. The iPLEDGE Program system verifies that all criteria have been met by the prescriber, patient, and pharmacy prior to granting the pharmacy authorization to fill and dispense isotretinoin. The pharmacist must obtain authorization from the iPLEDGE Program system via the internet (www.iPLEDGEprogram.com), telephone (1-866-495-0554) or through electronic telecommunication verification (via submission of an isotretinoin prescription claim) prior to dispensing each isotretinoin prescription for both male and female patients.

iPLEDGE Terms of Use | Safety Notice | Non-Compliance Action Policy | ©2016 iPLEDGE
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:
- Patient Introduction Brochure
- Prescriber Isotretinoin Educational Kit
- Dr. Reddy’s Zenatane Package Insert
- Mylan Amnesteem Package Insert
- Ranbaxy Abercaza Package Insert
- Ranbaxy Sotral Package Insert
- Teva Claravis Package Insert
- VerisPharm Myorisan Package Insert

Lessons Learned:
- About Levallois Medication
- About Birth Control
- About Post-Treatment Pregnancy Testing

Manufacturers’ Toll-free Numbers
For more information about the specific brands of isotretinoin, call the individual manufacturers at these numbers.

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnesteem™</td>
<td>Mylan Pharmaceuticals Inc.</td>
<td>1.800-796-9526</td>
</tr>
<tr>
<td>Claravis™</td>
<td>Teva Pharmaceuticals USA.</td>
<td>1.800-227-7522</td>
</tr>
<tr>
<td>Sotral®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1.800-406-7984</td>
</tr>
<tr>
<td>Myorisan®</td>
<td>VerisPharm Incorporated</td>
<td>1.877-254-4381</td>
</tr>
<tr>
<td>Abercaza®</td>
<td>Ranbaxy Laboratories, Inc.</td>
<td>1.800-406-7984</td>
</tr>
<tr>
<td>Zenatane™</td>
<td>Dr. Reddy’s Laboratories, Ltd.</td>
<td>1.888-375-3784</td>
</tr>
</tbody>
</table>
Public – Find a Participating Pharmacy

Find a Participating Pharmacy

Please enter any or all search criteria and click the Search button.

Sp  City  State

Search
Public – FAQs

Frequently Asked Questions (FAQ)

iPLEDGE PROGRAM (click topics below for more information)
A. TECHNICAL ASSISTANCE
B. PATIENT
C. PHARMACY
D. PRESCRIBER
E. ALL USERS
Common – 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 in 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. “Prescribers” are prescribers that prescribe restricted distribution drugs pursuant to the IPledge Program. “Designated Agents” are persons designated by Prescribers to act on their behalf with the IPledge Website. Pharmacists are pharmacists that utilize the IPledge Website to verify a patient’s enrollment in IPledge and status before filling a prescription at a retail pharmacy.

These Terms of Use are between a user of any portion of the Site (“you” or “your”) and the sponsors of the Site (“IPledge” “we”, “us” and “our”).

Registration and Assent

Access to and use of the Site is conditioned upon your assent to these Terms of Use. You are deemed to have assented to these Terms of Use when you use any available page of the Site. You are deemed to have assented to these Terms of Use as applicable to the IPledge Website, when you complete the online registration processes required for Registered Users and indicate during the registration process that you accept these Terms of Use along with the Privacy Policy incorporated therein. You are deemed to have accepted these Terms of Use each time you access the Site and each time you use your login credentials to access the IPledge Website portion of the Site. By registering for or otherwise accessing or using the Site, you acknowledge that you have read, understand, and agree to be legally bound by these Terms of Use. These Terms of Use and the Privacy Policy are available during registration for the IPledge Website and on various pages of the Site.

Updates

Any amendments to these Terms of Use and the Privacy Policy will be posted on the Site. These Terms of Use, the Privacy Policy, and the other policies and guidelines in effect when you access the Site, govern your use of the Site.

Welcome

Have Questions? Call our toll-free number 1.866.495.0604

The Only Way

About Isotretinoin

About IPledge

Prescriber Information

Find a Participating Pharmacy

FAQs
Common – 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 nasal bleeding. 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.
Public – Forgot Password

Forgot Password

Username

Submit

If you cannot remember your Username, please select your user type.

User Type

© 2014 iPLEDGE
User login timed out

Login Required

Login for registered users

Username
Password

I understand and will comply with:
• iPLEDGE Terms of Use
• Non-Compliance Action Policy

Login

Forgot Password?