Most Recent Modification: July 2016

The iPLEDGE Program

Isotretinoin Educational Kit For Female Patients Who Can Get Pregnant

The Importance Of Avoiding Pregnancy On Isotretinoin

The tools you need to help you prepare, plan treatments, and prevent pregnancies during the course of isotretinoin treatment

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

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

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

CONTENTS

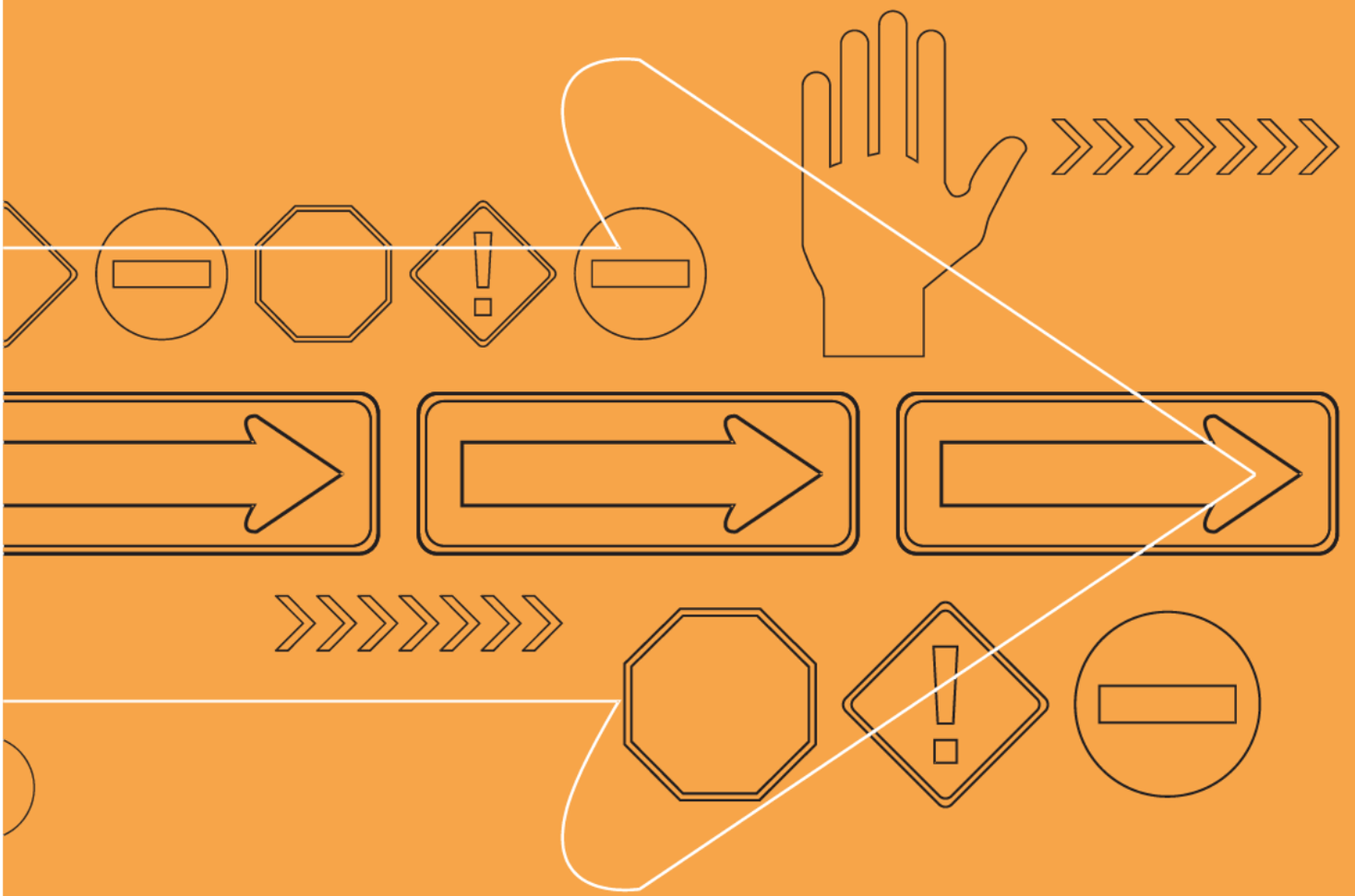
- Guide To Isotretinoin For Female Patients Who Can Get Pregnant
- Birth Control Workbook
- Contraception Referral Form And Contraception Counseling Guide
- Patient Identification Card
- Patient Information/Informed Consent (for all patients)
- Patient Information/Informed Consent About Birth Defects (for females who can get pregnant)
- Patient Flowchart

iPLEDGE™

Committed to Pregnancy Prevention

Reference ID: 3956479

Guide To Isotretinoin For Female Patients Who Can Get Pregnant



› The guide to help you prepare, plan treatments, and prevent pregnancies during the course of isotretinoin treatment

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iPLEDGE™
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Guide To Isotretinoin For Female Patients Who Can Get Pregnant

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ABOUT ISOTRETINOIN

Isotretinoin (eye-soh-tret-in-OH-in) treats a type of severe acne called nodular acne that other treatments, including antibiotics, have not helped. It comes in a capsule you take by mouth. Treatment usually lasts 4 to 5 months.

Isotretinoin can cause serious side effects, including birth defects. There is a very high chance of birth defects if an unborn baby's mother takes isotretinoin. The goal of the iPLEDGE Program is to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin. The program involves a set of steps that you, your doctor, and your pharmacist must follow for you to take isotretinoin.

Before starting isotretinoin, talk with your doctor about how isotretinoin can help your skin and about the side effects. Read this *iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and the other materials in this educational kit. Your doctor also has an educational video for you to watch.

Make sure you understand the requirements of the iPLEDGE Program. Then, decide if isotretinoin is right for you.

ISOTRETINOIN AND BIRTH DEFECTS: FOR FEMALE PATIENTS WHO CAN GET PREGNANT

Here are 2 key messages of the iPLEDGE Program:

Do NOT take isotretinoin if you are pregnant.

Do NOT get pregnant before starting isotretinoin, while taking it, and for 1 month after your last dose.

If you get pregnant while taking isotretinoin, there is a very high chance that your baby will be deformed, born too early, or die before being born. This can happen even if you only take isotretinoin for a short time.

Prevent Pregnancy And Birth Defects

Here are some key steps you must follow in the iPLEDGE Program to take isotretinoin:

Have 2 negative pregnancy tests before you start isotretinoin.

Have a negative pregnancy test before you obtain each monthly prescription.

Use 2 forms of birth control together.

You must use 2 forms of birth control together correctly all the time for 1 month before you start isotretinoin, while you are taking isotretinoin, and for 1 month after your last dose. These forms of birth control must be effective in the iPLEDGE Program.

Any form of birth control can fail. Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.

Your doctor will talk with you about birth control or refer you to a gynecologist, a family doctor, or a birth control expert for counseling.

Reasons you would not have to use 2 forms of birth control

There are 2 reasons you would not have to use 2 effective forms of birth control.

- You commit to not having any heterosexual sexual intercourse with a male for 1 month before, during, and for 1 month after your isotretinoin treatment (abstinence).
- You are unable to get pregnant because:
  - You have entered menopause, and your doctor has confirmed this.
  - You have had both of your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant woman receives blood that you donated. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin With Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects.

See the *Safety Information* section on page 14 for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

THE iPLEDGE WEB SITE AND PHONE SYSTEM

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant and your patient educational kit are resources for the information you need about isotretinoin and the iPLEDGE Program. The iPLEDGE Program also has a web site and an automated phone system.

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

The information on the phone system is available in English and Spanish. You can get general information about isotretinoin and the iPLEDGE Program right away. When you start taking isotretinoin, your doctor will give you a patient ID number and ID card, and other program materials. You use these to log in to the system *(see page 9)*. You will use the system to meet some of the monthly requirements of the program.

After you have been registered in the iPLEDGE Program by your doctor, you will receive your iPLEDGE password in the mail in 5 to 10 business days. Follow the instructions that come with the password to access the iPLEDGE Program system.

KEY INFORMATION FOR PATIENTS

The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant explains the key information about the iPLEDGE Program before, during, and after your isotretinoin treatment. Here is a general overview:

1. Learn about the iPLEDGE Program and the isotretinoin side effects and risks in pregnancy.
2. Sign the Patient Information/Informed Consent forms.
3. Plan for treatment and for monthly appointments and pregnancy tests.
4. Choose 2 forms of effective birth control for the iPLEDGE Program; use them all of the time.
5. Take blood or urine pregnancy tests.
6. Answer monthly educational questions to show you understand the iPLEDGE Program and about preventing pregnancy.
7. Follow requirements for pregnancy testing and follow-up after your last dose.
8. Do not donate blood during your treatment or for 1 month after your last dose.
9. Do not share isotretinoin.

This information and details of the program are described in the sections to follow. The section on page 6 reviews the forms of effective birth control in the iPLEDGE Program.

You can always use the checklist on the next page as a quick reminder of the program information.

THE iPLEDGE PROGRAM CHECKLIST

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

Female patients who can get pregnant…

The prescription window is 7 days, and starts on the date that the urine or blood sample *is taken for your pregnancy test. This date is counted as DAY 1.*

To determine the end date of your 7-day prescription window, you should add 6 days to the date of the blood or urine sample being taken.

After 11:59 p.m. Eastern Time on the last day of the 7-day prescription window, you can no longer obtain your prescription, and must start the process over to get a new 7-day prescription window.

All patients have a specific period of time in which they can Obtain their prescription.

Before Starting Treatment

PLANNING

- ❑ **Plan** your course of treatment (about 4 to 5 months). (*see page 8*)
- ❑ **Talk** with your doctor about the iPLEDGE Program.
- ❑ **Sign** the Patient Information/Informed Consent (for all patients) form.
- ❑ **Have** your first urine or blood pregnancy test, which can be performed at the doctor's office.
- ❑ **Get** your patient ID cards containing your patient ID number from your doctor. (*see page 8*)

BIRTH CONTROL (*see page 6*)

- ❑ **Read** *The iPLEDGE Program Birth Control Workbook.*
- ❑ **Talk** with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options.
- ❑ **Choose** 2 effective forms of birth control.
- ❑ **Start** using the 2 forms of birth control together for at least 1 month before you start isotretinoin.

YOUR FIRST PRESCRIPTION

- ❑ **Have** a second pregnancy test within the first 5 days of your menstrual period (at least 30 days after registration).
- ❑ **Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form. (*see page 9*)
- ❑ **Answer** questions about the iPLEDGE Program and confirm your 2 forms of birth control. (see page 10) This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.
- ❑ **Obtain** your prescription for up to a maximum of a 1-month supply. (*see page 11*)
- ❑ Obtain your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1. (*see page 12*)
  - If you are not able to obtain your first prescription within the 7-day prescription window, you will be required to wait a minimum of 19 days before you can start this process again.
- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ Answer different questions each month about the iPLEDGE Program.

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During Treatment

- ❑ **Use** 2 effective forms of birth control together all the time.
- ❑ **See** your doctor for a monthly pregnancy test.
- ❑ **Keep** your appointments every month to get a prescription.
- ❑ **Confirm** your 2 forms of birth control by entering them into the iPLEDGE Program System. (see page 10)
- ❑ **Answer** different questions each month about the iPLEDGE Program. **This cannot be completed until after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- ❑ **Obtain** your prescription for up to a maximum of a 30-day supply. *(see page 11)*
- ❑ **Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1. (*see page 12*)
  - If you do not obtain your prescription within the 7-day prescription window, you will need to go back to your doctor to start this process again.
- ❑ **Do not donate** blood.

After Treatment

RIGHT AFTER YOUR LAST DOSE (*see page 13*)

- ❑ **Get** a pregnancy test after your last dose.
- ❑ **Continue** using your birth control for 1 month.
- ❑ **Do not donate** blood for 1 month after your last dose.
- ❑ **Ensure** that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

1 MONTH AFTER YOUR LAST DOSE

- ❑ **Have** a final pregnancy test at 1 month after your last dose.
- ❑ Ensure that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System.

EFFECTIVE FORMS OF BIRTH CONTROL

Not all forms of birth control are acceptable while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read The iPLEDGE Program Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read *The iPLEDGE Program Birth Control Workbook*. Discuss this information with someone you trust. Discuss it with your partner. Think about what forms of birth control you would really use, and then talk with your doctor or a birth control expert.

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Talk With An Expert

If you want to talk to a birth control expert, your gynecologist, or family doctor about birth control, the doctor who prescribes isotretinoin for you can refer you. The makers of isotretinoin will pay for a visit for you to talk about birth control. *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* is in this booklet.

- Make an appointment with a birth control expert, your gynecologist, or family doctor.
- Take *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide* with you. It has important information that the birth control expert, gynecologist, or family doctor needs to talk about, including the forms of effective birth control for the iPLEDGE Program.
- The healthcare professional providing contraception counseling will fill out the Contraception Referral Form included in the guide after he/she talks with you and then mail or fax it back to the doctor who prescribes your isotretinoin.

Changing Your Birth Control

If you need to change forms of birth control during your isotretinoin treatment, you need to tell the doctor who prescribes your isotretinoin. You do not want to take isotretinoin if you are not protected against pregnancy all the time.

You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been on the new form for at least 1 month and have a negative pregnancy test.

Changing From Abstinence

If you have been abstinent (not having any sexual activity) and you decide to start having sexual activity, you must tell the doctor who prescribes your isotretinoin. You and your doctor must make a plan to start birth control and be sure you are not pregnant before you continue isotretinoin.

One of the most common reasons that women get pregnant is that they do not avoid sexual activity when they plan to be abstinent.

Video: *Be Prepared, Be Protected, And Be Aware: The Risk Of Pregnancy While On Isotretinoin*

Your doctor has a video that shows the kinds of birth defects that may happen if a woman takes any amount of isotretinoin while she is pregnant. It also reviews the steps for preventing pregnancy.

THE iPLEDGE PROGRAM CHECKLIST INFORMATION

Plan Your Course Of Treatment

Birth Control and Pregnancy tests

Before you can begin isotretinoin therapy, there is a 30-day wait period where you must be on two forms of birth control. Additionally, you need to have 2 negative pregnancy tests. They can be urine or blood tests. You will need to plan with your doctor when and where to take your pregnancy tests.

- You take the first test when you decide to take isotretinoin.
- You take the second test during the first 5 days of the menstrual period right before you start isotretinoin. This pregnancy test must be done by an approved lab. The interval between the two tests must be at least 19 days.

You also take a pregnancy test every month done by an approved lab during treatment. You also take a pregnancy test after your last dose, and 1 month after your last dose. You will need to plan with your doctor when to take your pregnancy test each month.

Prescriptions

The most isotretinoin you can get at any one time is up to a maximum of a 30-day supply. You will need to see your doctor each month to get a new prescription, and meet the monthly program requirements.

Get Your Patient ID Number And Cards

Your doctor will give you your patient ID number and cards when you start the iPLEDGE Program. The ID cards are included in the back of this booklet. Tear out one card and keep it in a safe place. You can use the other cards in the booklet if you lose your card. It is important not to lose these cards. Write your number down as soon as you receive it and keep it where you will be able to find it.

You need your ID number and card:

- When you take your prescription to be filled at the pharmacy
- When you log in to the iPLEDGE Program automated system, either the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**

About The iPLEDGE Program Automated System

The first time you login to the iPLEDGE Program (either the web site or phone line) you will be asked to select a personal password and select a Date of Personal Significance. The selection of a personal password is a security feature that ensures that only you will know your password. A Date of Personal Significance is collected by the system to be used in verifying your identity should you require assistance from the iPLEDGE Call Center while using the iPLEDGE Program system.

Both your password and your Date of Personal Significance should be something that you will find easy to remember.

You can access the system to:

- Find a pharmacy where you can obtain up your prescription
- Change to a new doctor
- Get information about isotretinoin
- Answer your Comprehension Questions, required before you can obtain your prescription
- View information about your current status, your 7-day prescription window, and next steps required in the program
- View FAQ's (Frequently Asked Questions)

If you lose your patient ID cards, and cannot remember your patient ID number, contact your doctor.

Informed Consents

You sign 2 consent forms to be in the iPLEDGE Program.

1. **Patient Information/Informed Consent (for all patients)**

Signing the Patient Information/Informed Consent (for all patients) form means you understand that there are risks with isotretinoin.

2. **Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)**

Your doctor will talk to you about the risks of isotretinoin during pregnancy. You must also get this information in writing. You must understand that a baby exposed to isotretinoin could have severe birth defects. Signing the consent form means the following:

- You understand the risks of isotretinoin for unborn babies.
- You agree to use 2 effective forms of birth control, as the iPLEDGE Program requires. *The iPLEDGE Program Birth Control Workbook* has the list of effective forms.

The iPLEDGE Program Pregnancy Registry

Because isotretinoin causes such severe birth defects, it is very important for us to know about all the pregnancies that happen during treatment and within 1 month after the last dose. If you think you are pregnant call your doctor. The confidential iPLEDGE Program Pregnancy Registry is a way to collect that information. It may help us prevent more pregnancies in the future.

Your doctor will tell you about the confidential iPLEDGE Program Pregnancy Registry. You are encouraged to contact the iPLEDGE Program Pregnancy Registry at 1-800-681- 7247 if you get pregnant.

Answering Questions About The iPLEDGE Program And Preventing Pregnancy

The iPLEDGE Program requires you to answer comprehension questions before obtaining every prescription. These questions will demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen and the risks associated with isotretinoin. **You will not be able to answer your questions until your doctor has entered your pregnancy test result in the iPLEDGE Program System.** You may not obtain up your prescription until you have correctly answered the questions. You may use your iPLEDGE Program educational kit as a resource as you answer the questions.

Your First Month Taking Isotretinoin

The first month that you answer your questions, you will be asked a series of questions about iPLEDGE Program information and counseling provided to you. There are no wrong answers to these questions. The answers are used to determine how often the iPLEDGE Program materials are shared with patients.

Birth Control Verification

You must enter the 2 forms of birth control you are using. Your doctor will also separately enter the 2 forms of birth control you told him or her you are using. This information must be in the iPLEDGE Program system and must match for you to obtain your prescription.

Comprehension Questions

Before each prescription can be obtained from the pharmacy, you will have different questions about the iPLEDGE Program and preventing pregnancy to answer. You answer the questions in the iPLEDGE Program system using the web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654** within the 7-day prescription window.

You can use *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* and *The iPLEDGE Program Birth Control Workbook* to help you with the answers.

You need your patient ID number and password to log in to the iPLEDGE Program system.

To answer questions on the iPLEDGE Program web site:

1. Log in
2. Click on the button under "Answer the Questions"
3. Enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

To answer the questions on the iPLEDGE Program phone system:

1. Log in
2. Select the option to "Demonstrate Your Program Knowledge"
3. Follow the prompts to enter the 2 forms of birth control you are using
4. Follow the prompts to answer the questions

The system will let you know if you answered correctly. If you missed any questions, you will get to try other questions like the ones you missed. You must answer the questions correctly before you will be able to obtain your prescription.

If you miss a question again, the system will tell you where to look in *The iPLEDGE Program Guide To Isotretinoin For Female Patients Who Can Get Pregnant* or *The iPLEDGE Program Birth Control Workbook* to find answers. You can answer the questions again later. You may also talk with your doctor about questions you missed.

Obtain Your Prescription

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

The web site, **www.ipledgeprogram.com**, has a list of registered and activated pharmacies. Log in and choose "Finding a Participating Pharmacy" on the Patient home page.

The pharmacist will contact the iPLEDGE Program system before filling the prescription. The system tells your pharmacist if you can get isotretinoin. It will not tell the pharmacist any personal information about you.

You can only obtain your prescription for isotretinoin if:

- Your pregnancy test was negative
- Your doctor entered your 2 forms of birth control in the iPLEDGE Program system

- You answered your questions correctly. **This can only be done after your doctor has entered your pregnancy test result in the iPLEDGE Program System.**
- You also entered your 2 forms of birth control

You **obtain** the prescription within the 7-day prescription window (1 week) of the date of your pregnancy test, counting the date of the pregnancy test as DAY 1.

To figure out the last date you can obtain your prescription, add 6 to the date of your pregnancy test. For example:

Day 1 pregnancy test	Day 2 – Day 6	Day 7 – Last day obtain Day of the up prescription
(Friday, March 1)	(Saturday–Wednesday)	(Thursday, March 7)

The 7-day prescription window expires at 11:59 p.m. Eastern Time on Day 7 of the prescription window. Your pharmacist will not be able to fill your prescription after this time. If your 7-day prescription window expires before you obtain your prescription, you can start a new 7-day prescription window right away (unless it is your first prescription window), but you must repeat the program requirements to get another prescription. Additional information regarding the specific dates of your 7-day prescription window, and other information about your current status can be found by selecting "My Program Status" on the website from the Patient home page (after you log in).

Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack.

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

After Your Last Dose

It is very important that you:

- Get a pregnancy test.
- Keep using 2 effective forms of birth control together all the time for 1 month after your last dose. It takes time for isotretinoin to leave your bloodstream.
- Go back to your doctor 1 month after your last dose for your last pregnancy test, even if you think you are not pregnant. If you miss this appointment, you will receive a reminder notification.
- Do not give blood for 1 month after your last dose.
- If your doctor does not enter the results of the pregnancy test after your last dose, and does not enter the pregnancy test 1 month after your last dose, both you and your doctor will be contacted for additional information.

Changing To A New Doctor

You can change your doctor (Primary Prescriber) in the iPLEDGE Program system. Once you make the change, you will not be able to get any more prescriptions from your original doctor.

You can change your doctor through the iPLEDGE Program web site, **www.ipledgeprogram.com**, or automated phone line, **1-866-495-0654**. You need your patient ID number to log in to the system.

To change your doctor on the iPLEDGE Program web site:

1. Log in
2. Choose "Change Primary Prescriber" from the menu
3. You need to enter the following information about your new doctor:
   - First and last name
   - City
   - Phone number

To change your doctor on the automated phone line:

1. Log in
2. Select the Option for "More Choices"
3. Select the Option to "Change Your Prescriber"
4. Follow the prompts to enter the new information

The system will tell you if you have made the change correctly. The new doctor must accept you as a patient within the iPLEDGE Program system before being able to give you a prescription.

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Safety Information

ABOUT ISOTRETINOIN

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ISOTRETINOIN?

- Isotretinoin is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because isotretinoin can cause birth defects, isotretinoin is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE Program.
- Isotretinoin may cause serious mental health problems.

1. **Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** Female patients who are pregnant or who plan to become pregnant must not take isotretinoin.
Female patients must not get pregnant:
   - For 1 month before starting isotretinoin
   - While taking isotretinoin
   - For 1 month after stopping isotretinoin

If you get pregnant while taking isotretinoin, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The iPLEDGE Program Pregnancy Registry at 1-866-495-0654

2. **Serious mental health problems.** Isotretinoin may cause:
   - **Depression**
   - **Psychosis** (seeing or hearing things that are not real)
   - **Suicide**
   Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

After stopping isotretinoin, you may also need follow-up mental health care if you had any of these symptoms.

What Is Isotretinoin?

Isotretinoin is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin can cause serious side effects. (See **"What is the most important information I should know about isotretinoin?"**) Isotretinoin can only be:

- Prescribed by doctors that are registered in the iPLEDGE Program
- Dispensed by a pharmacy that is registered with the iPLEDGE Program
- Given to patients who are registered in the iPLEDGE Program and agree to do everything required in the program

What Is Severe Nodular Acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who Should Not Take Isotretinoin?

- **Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment.** Isotretinoin causes severe birth defects. (See "**What is the most important information I should know about isotretinoin?**")
- **Do not take isotretinoin if you are allergic to anything in it.**

What Should I Tell My Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental problems
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss (osteoporosis) or weak bones
- An eating problem called anorexia nervosa (where people eat too little)
- Food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Isotretinoin must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Isotretinoin and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with isotretinoin can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take isotretinoin. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with isotretinoin may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with isotretinoin may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

These medicines should not be used with isotretinoin unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How Should I Take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the iPLEDGE Program. Before prescribing isotretinoin, your doctor will:

- Explain the iPLEDGE Program to you.
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the iPLEDGE Program.

- You will get no more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the isotretinoin iPLEDGE Program. You should talk with your doctor each month about side effects.
- The amount of isotretinoin you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take isotretinoin 2 times a day with a meal, unless your doctor tells you otherwise. Swallow your isotretinoin capsules whole with a full glass of liquid. Do not chew or suck on the capsule. Isotretinoin can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do not take 2 doses at the same time.
- If you take too much isotretinoin or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking isotretinoin. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious side effects from isotretinoin. Female patients who can get pregnant will get a pregnancy test each month.
- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking isotretinoin. You must access the iPLEDGE Program system to answer questions about the program requirements and to enter your 2 chosen forms of birth control. To access the iPLEDGE Program system, go to www.ipledgeprogram.com or call 1-866-495-0654.

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this *free* visit, which will be paid for by the company that makes isotretinoin.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using isotretinoin and call your doctor right away.

What Should I Avoid While Taking Isotretinoin?

- **Do not get pregnant** while taking isotretinoin and for 1 month after stopping isotretinoin. (See **"What is the most important information I should know about isotretinoin?"**)
- **Do not breastfeed** while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.
- **Do not give blood** while you take isotretinoin and for 1 month after stopping isotretinoin. If someone who is pregnant gets your donated blood, her baby may be exposed to isotretinoin and may be born with birth defects.
- **Do not take other medicines or herbal products** with isotretinoin unless you talk to your doctor. (See **"What should I tell my doctor before taking isotretinoin?"**)
- **Do not drive at night until you know if isotretinoin has affected your vision.** Isotretinoin may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using isotretinoin and for at least 6 months after you stop.** Isotretinoin can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Isotretinoin may make your skin more sensitive to light.
- **Do not share isotretinoin with other people.** It can cause birth defects and other serious health problems.

What Are The Possible Side Effects Of Isotretinoin?

- **Isotretinoin can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Isotretinoin may cause serious mental health problems.** (See **"What is the most important information I should know about isotretinoin?"**)
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
  - Bad headache
  - Blurred vision
  - Dizziness
  - Nausea or vomiting
  - Seizures (convulsions)
  - Stroke
- **Skin problems.** Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pink eye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **Stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking isotretinoin. Stop taking isotretinoin and call your doctor if you get:
  - Severe stomach, chest, or bowel pain
  - Trouble swallowing or painful swallowing
  - New or worsening heartburn
  - Diarrhea
  - Rectal bleeding
  - Yellowing of your skin or eyes
  - Dark urine
- **Bone and muscle problems.** Isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
  - Back pain
  - Joint pain
  - A broken bone. Tell all healthcare providers that you take isotretinoin if you break a bone.

Stop isotretinoin and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Isotretinoin may stop long bone growth in teenagers who are still growing.

- **Hearing problems.** Stop using isotretinoin and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **Vision problems.** Isotretinoin may affect your ability to see in the dark. This condition usually clears up after you stop taking isotretinoin, but it may be permanent. Other serious eye effects can occur. Stop taking isotretinoin and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking isotretinoin and after treatment.
- **Lipid (fats and cholesterol in blood) problems.** Isotretinoin can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when isotretinoin treatment is finished.
- **Serious allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **Blood sugar problems.** Isotretinoin may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **Decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of isotretinoin** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with isotretinoin. Your doctor or pharmacist can give you more detailed information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How Should I Store Isotretinoin?

- Store isotretinoin at room temperature. Protect from light.
- **Keep isotretinoin and all medicines out of the reach of children**.

General Information About Isotretinoin

Do not use isotretinoin for a condition for which it was not prescribed. Do not give isotretinoin to other people, even if they have the same symptoms that you have. It may harm them.

This safety section summarizes the most important information about isotretinoin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about isotretinoin that is written for health care professionals. You can also call iPLEDGE Program at **1-866-495-0654** or visit **www.ipledgeprogram.com**.

For More Information About Isotretinoin And The iPLEDGE Program

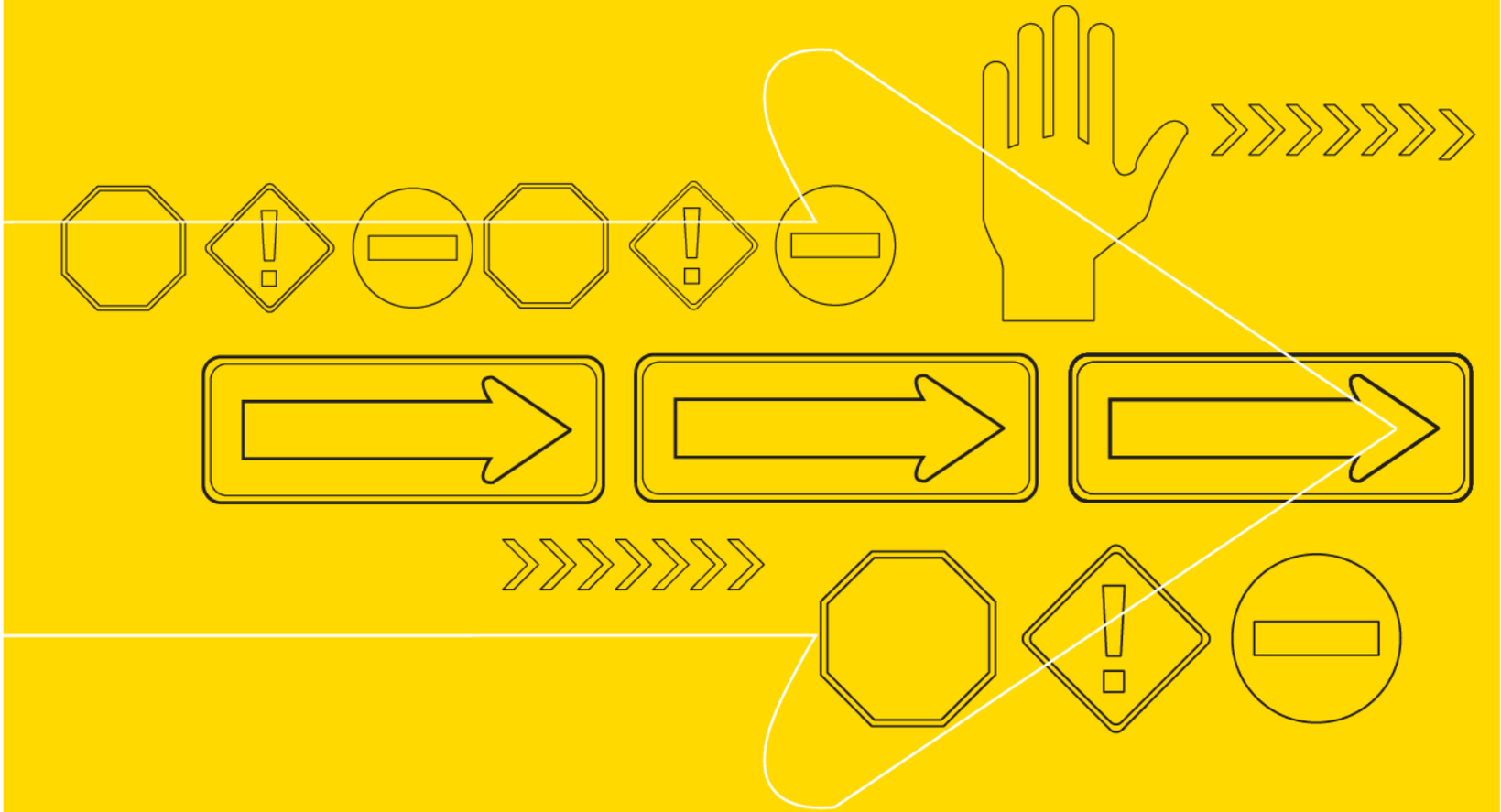
If you have questions about the iPLEDGE Program, ask your doctor, visit the iPLEDGE Program web site at **www.ipledgeprogram.com**, or call the automated phone line at **1-866-495-0654**.

For private birth control information, you can reach the iPLEDGE Program automated phone line 24 hours a day, 7 days a week at 1-866-495-0654. You can learn about different subjects, including:

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

Isotretinoin Products

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



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

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

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

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

iPLEDGE™

Committed to Pregnancy Prevention

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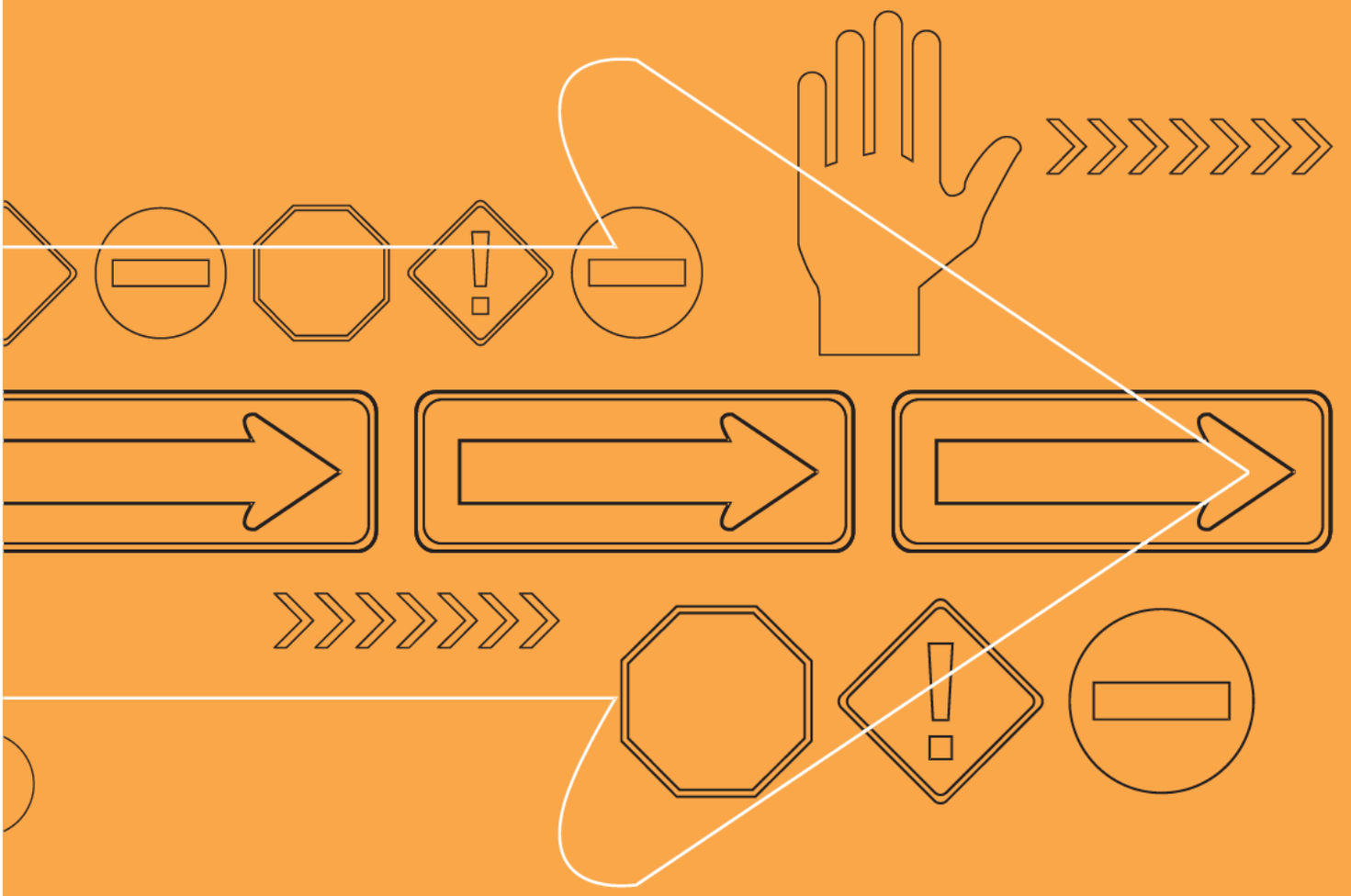
Reference ID: 3956479

Birth Control Workbook



› The guide to help you decide which forms of birth control are best for you

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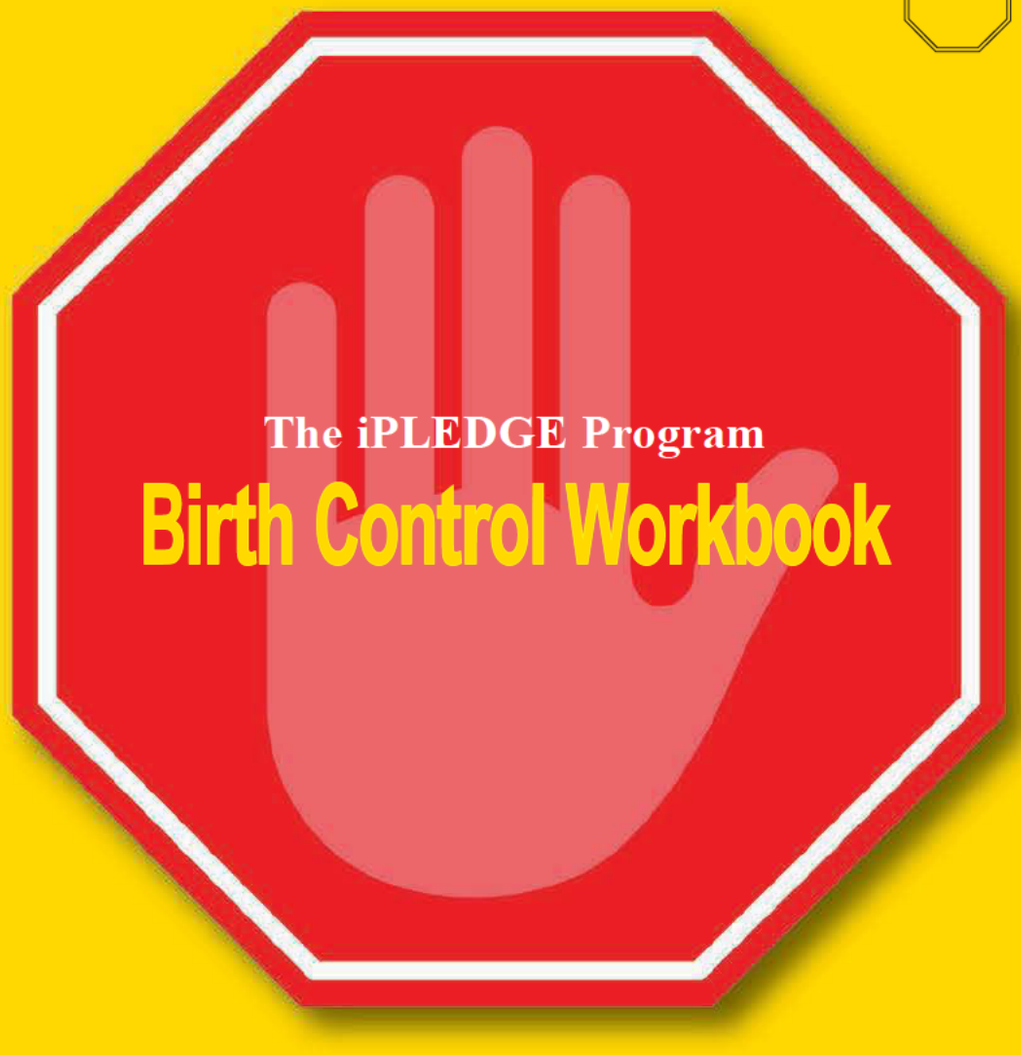

The iPLEDGE Program

Birth Control Workbook

The guide to help you decide which forms of birth control are best for you during treatment with isotretinoin

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

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The iPLEDGE Program Birth Control Workbook

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PREVENTING PREGNANCIES

Not all forms of birth control are effective while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

Read This Birth Control Workbook

To find out what birth control is effective for the iPLEDGE Program, read this *iPLEDGE Program Birth Control Workbook*. Read it before you make any decisions about birth control. Read it even if you are already using birth control. Read it even if you think you will not have sex with a male for your whole isotretinoin treatment.

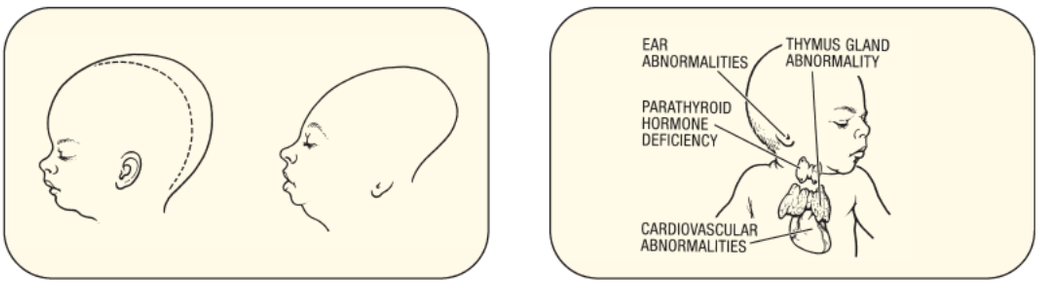
After you have read through the booklet, talk it over with someone you trust. Think about what kinds of birth control you would really use. Then talk with your doctor or a birth control expert.

Share this workbook with your partner. Talk with your partner about birth defects and isotretinoin. Explain what you both need to do to prevent pregnancy. Tell him you need to prevent pregnancy for at least 1 month before you start isotretinoin, during your treatment, and for 1 month after your last dose. This can be several months.

Write down a list of questions for your dermatologist, gynecologist, or family doctor. No question is too silly. Make sure you know how to use the birth control forms you choose.

WHY SHOULD I USE THIS WORKBOOK?

You are getting ready to start isotretinoin (eye-soh-tret-in-OH-in). It treats severe acne, but it can also cause birth defects. You must not get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose. **There is a very high chance that your baby could be deformed, born too early, or die.** This can happen even if you take isotretinoin for only a short time.



The pictures show some of the birth defects your baby can have. Your baby's head could be deformed; the ears could be an odd shape or even missing. The eyes could be too far apart, the bridge of the nose too low, or the chin smaller than normal. The baby could have mental retardation or severe problems in the glands, heart, and brain.

You do not want to be pregnant or get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose.

To keep from getting pregnant, you need to use 2 effective forms of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- While you take it—treatment usually lasts 4 to 5 months
- For 1 month after your last dose—you still need protection against pregnancy

This workbook is for ALL female patients who can possibly get pregnant. This means that:

- You are physically able to get pregnant
- You have a uterus and ovaries
- You have menstrual periods

Even if you are not having sex, you still need to follow the requirements of the iPLEDGE Program.

Female Patients Who Cannot Get Pregnant

Female patients who cannot get pregnant are not required to be on birth control. This applies to you if:

- You have entered menopause, and your doctor has confirmed this.
- You have had your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.

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HOW SHOULD I USE THIS WORKBOOK?

Use this workbook as a guide to help you decide which 2 effective birth control forms are best for you during your treatment. You will want to pick a birth control form that works for you and gives you the best protection against pregnancy (primary form). Since all forms of birth control can fail, you must also pick a second form (another primary form or a secondary form) that you use every time you have sex.

This workbook also provides information about abstinence, emergency birth control, and issues around conception and pregnancy.

THE iPLEDGE PROGRAM AND BIRTH CONTROL

Referral for birth control counseling

Before beginning treatment, you or the doctor may choose a referral to a birth control expert. The makers of isotretinoin will pay for 1 visit for birth control counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the birth control requirements and the effective forms of birth control of the iPLEDGE Program for the birth control expert. The referral form should be taken with you to the birth control counselor.

Why Do I Have To Use 2 Forms Of Birth Control Together?

- Any single birth control form can fail.
- Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.
- Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control!

Can I Use Any 2 Forms Of Birth Control?

No, you must choose from the iPLEDGE Program list of effective birth control forms.

The 2 types of birth control you use for the iPLEDGE Program are called **primary forms** and **secondary forms**.

- **Primary forms** do not fail very often. Be sure to choose a primary form that gives you the lowest chance of failure. This depends on such things as how well you remember to take medicine every day, whether you have had children or your partner has had a vasectomy, or you have medical problems.
- **Secondary forms** include **barrier forms** and **other forms** of birth control. The most important thing about a secondary form is using it every time you have sex.
  - **Barrier forms** keep sperm from entering the uterus. Barrier forms include the diaphragm and the cervical cap, both of which must be used with a cream that kills sperm, called a spermicide. The Male Latex Condom is also a Barrier form, and it can be used with or without spermicide.
  - **Other forms** (vaginal sponge) contain spermicide.

Preventing Pregnancy By Abstinence (Not Having Sex)

Abstinence means that you ***will not have sex*** or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do, especially if you are used to having sex.

It is easier not to have sex when it is a lifestyle choice, such as religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence).

If you cannot commit completely to not having sex (abstinence) while taking isotretinoin, you must use 2 separate, effective forms of birth control at the same time. The only exceptions are if you have had surgery to remove your uterus (a hysterectomy) or both of your ovaries (bilateral oophorectomy), or if your doctor has medically confirmed that you are post-menopausal. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE Program.

Concerns About Birth Control Pills

Many female patients use birth control pills. But birth control pills can fail, and you can get pregnant. They fail because you may forget to take them as directed by your health care provider.

- If you take them about the same time every day, they are very effective birth control.
- If you miss pills and do not take them every day, your chance of getting pregnant is much higher with birth control pills than with other primary birth control forms, such as hormonal shots or an intrauterine device (IUD).

If you are taking birth control pills, do you remember to take them every day? If not you need to consider another primary form of birth control as you read this workbook.

The iPLEDGE Program Effective Birth Control Forms

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

Primary forms	Secondary forms
• Tubal sterilization (tying your tubes) • Partner's vasectomy • Intrauterine device • Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)	*Barrier forms (always used with spermicide)* • Diaphragm • Cervical cap *Barrier form (used with or without spermicide)* • Male latex condom *Others:* • Vaginal sponge (contains spermicide)

You cannot use 2 hormonal forms together. Progesterone-only "mini-pills" are not considered an effective form of birth control for the iPLEDGE Program.

Female condoms are not an effective secondary form of birth control for the iPLEDGE Program.

Reference ID: 3956479

Birth Control Forms That Are NOT Acceptable

You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

- Birth control pills without estrogen (progesterone-only mini-pills)
- Female condoms
  - *A thin, loose-fitting, and flexible plastic tube that you put inside your vagina. It covers your cervix to block sperm.*
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
  - *This means not having sex during certain times of the month when you might be more likely to get pregnant. It does not work.*
- Withdrawal
  - *Your partner can leak enough sperm to get you pregnant even if he does not ejaculate inside you.*
- Cervical shield[‡]
  - *A silicone disc that sticks to your cervix to keep sperm out.*

Tell your doctor what type of birth control you are using. You will need to change to effective forms if your birth control is listed above. You must use 2 effective forms together all the time for at least 1 month and have a negative pregnancy test.

[‡] A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception See page 28

Ask yourself:

1. Which of the following is NOT one of the effective primary or secondary forms of birth control while taking isotretinoin?

   A) Partner's vasectomy or tubal sterilization (tying your tubes)

   B) Natural family planning

   C) Hormonal IUD

   D) Cervical cap with spermicide

2. Which of the following are effective forms of birth control for someone on isotretinoin?

   A) The hormonal skin patch and a male latex condom

   B) Cervical cap and a male latex condom

   C) Copper T380A IUD and withdrawal

   D) Birth control pills and a diaphragm with spermicide

Answer key: page 38

WHY DO I NEED HELP CHOOSING BIRTH CONTROL?

Not every birth control form is good for everyone. Some female patients should not use certain birth control, such as hormones or an IUD. If you are not good at remembering to take medicines, you should not choose birth control pills. Your dermatologist, gynecologist, or family doctor will help you choose the right forms for you. They will also give you exact instructions on how to use them.

Choose forms that you will actually use all the time. Some female patients have found it hard to use 2 forms of birth control together all the time. **This workbook will help you sort through these questions.** It will help you choose the 2 birth control forms that will be best for you. Here are some questions to think about.

Reference ID: 3956479

Ask yourself:

- Have you ever used birth control? Did you think you will need to use birth control someday?
- What birth control are you using now? Do you like it and want to continue using it?Is it on the list of effective birth control for the iPLEDGE Program?
- Are you currently having sex?
- Are you ever pressured into sex or think you may be forced to have sex?
- If you are taking birth control pills, do you ever forget to take them? Do you ever take them out of order? Do you always take medications the way you are told?
- Are there any forms of birth control you have heard about and would like to try?
- Can you rely on your partner's cooperation when using birth control, such as getting him to use a male latex condom each time you have sex?
- Are you worried about protecting yourself from STIs (sexually transmitted infections) or HIV (AIDS)?
- Is the cost of birth control a problem for you?
- Do you mind having to stop sex play to use a male latex condom or diaphragm?
- Do you worry about certain forms of birth control?
- Do you ever want to be pregnant?

What If I Cannot Use 2 Forms Of Birth Control Together All The Time?

Talk with your dermatologist, gynecologist, or family doctor. If you plan to have sex during your treatment and feel you cannot be 100% successful in using 2 forms of birth control each time, you should not take isotretinoin.

What If My Birth Control Fails?

The section on "Emergency Birth Control (Emergency Contraception)" is on page 31 of this workbook. It tells you what emergency birth control is and where to get it quickly.

Reference ID: 3956479

MAKING A CHOICE ABOUT BIRTH CONTROL

General Advice

Stay with your current primary form of birth control if:

- You are currently using an effective primary form AND you use it perfectly. For example, you do not miss birth control pills or hormone shots.
- You are satisfied with it.

Talk with your dermatologist, gynecologist, or family doctor about changing birth control before you start isotretinoin treatment if you:

- Do not use your current form of birth control perfectly. For example, you forget to change hormonal skin patches every week.
- Are not satisfied with the birth control you are using now. Changing birth control in the middle of your isotretinoin treatment is difficult.

You need to tell the doctor who prescribes your isotretinoin if you decide to change forms of birth control during treatment. You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been using the new form with a second form for at least 1 month and have a negative pregnancy test.

Planning Ahead With Your Partner

You want your partner to support you as you go through isotretinoin treatment. It is a great idea to talk with him about the iPLEDGE Program before you start. Do not surprise him later.

1. Talk to him about why you decided to take isotretinoin at this time.
2. You will want him to agree with and support your decision to have this treatment.
3. Make sure he knows all the facts about isotretinoin and birth defects. Show him the patient information. Your partner needs to understand all the facts about isotretinoin. He needs to be aware of what good it can do, as well as its risks.
4. Make sure he knows you have to use 2 forms of birth control together correctly all the time for at least 1 month before beginning isotretinoin treatment, during treatment for several months, and 1 month after the last dose of isotretinoin.
5. Make sure he is willing to go along with the iPLEDGE Program for several months.

You could ask your partner:

1. To help you make a list of questions to ask your doctor
2. To come with you to a doctor's office visit
3. To help you choose the 2 forms of birth control you will be using

Ask yourself:

1. Your doctor tells you that you need to have a pregnancy test before you can obtain a prescription. You would:
   - A) Refuse the test because you know you are not pregnant
   - B) Ask your doctor to explain why you need the test
   - C) Go to another doctor to get isotretinoin

2. I need to use 2 separate, effective forms of birth control at the same time while on isotretinoin because:
   - A) There is a high chance for multiple births from taking isotretinoin
   - B) There is a very high chance that my baby will be deformed if I get pregnant
   - C) I may find it hard to not have sex during treatment and 1 month after my last dose

3. You already take birth control pills. If you want to start isotretinoin, you:
   - A) Review this *iPLEDGE Program Birth Control Workbook*, and then get counseling before you choose a second form
   - B) Do not worry about a second form now, because you are not having sex with anyone

Answer key: page 38

PRIMARY FORMS OF BIRTH CONTROL

This section of the workbook provides information about the different forms of primary birth control. It only gives you the most important information you need for the iPLEDGE Program. It does not cover all the side effects or other information about these forms. If you want more information, ask your dermatologist, gynecologist, or family doctor. They have more information written for healthcare professionals and for patients.

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

Hormonal Birth Control Forms

Hormonal birth control forms include combination birth control pills, the skin patch, shots, under-the-skin implants, and the vaginal ring. They are prescription medicines that prevent pregnancy.

Hormonal Combination Birth Control Pills

Hormonal combination birth control pills are birth control pills you take by mouth every day as prescribed.

Progesterone-only birth control pills (mini-pills) are not acceptable for the iPLEDGE Program because they are not an effective form of birth control. If you are using these, you will have to choose another primary form of birth control.

Who should not take birth control pills?

You should not use birth control pills if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

Why is it important how I take birth control pills?

Birth control pills provide very good protection only if you take them about the same time every day and do not miss any pills. If you miss pills, your chance of pregnancy is much greater. Your chance of getting pregnant is higher if you miss pills at the beginning of your cycle or start your pills too late in your cycle. Less than half of all females take their birth control pills as prescribed.

- The most important thing about using birth control pills as your primary form of birth control is taking them every day to keep the chance of pregnancy as low as possible. If you have not used them perfectly, you may need to choose another primary form of birth control, such as the hormonal shot, an IUD, or a hormonal skin patch.
- Isotretinoin may make birth control pills less effective. That means you could be more likely to get pregnant while you are taking isotretinoin, particularly if you miss a pill.

Are you taking birth control pills now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you ever have pills left at the end of the month?
- How often do you miss more than 1 pill per cycle? Do you do it more than 2 cycles in a year?
- Have you ever taken birth control pills out of order?

If you answered yes to any of these questions, you probably need to choose another primary form of birth control.

If you are not taking birth control pills now, why do you think you want to try them? Ask yourself:

- Have you ever had to remember to take a pill every single day?
- Why do you think you can remember this task?

If you do not remember to take your pill every day without fail or have never taken pills every day before, you should probably not use birth control pills during isotretinoin treatment.

Advantages

- You may be able to get pregnant within 3 months after stopping birth control pills.
- Breast cysts may occur less frequently
- May provide some protection against the development of uterine and ovarian cancer

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Disadvantages

- Birth control pills do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- If you skip pills, your chance of pregnancy is very high.
- Isotretinoin, antibiotics, and St. John's Wort may make birth control pills less effective.

What should I do if I miss birth control pills when I am on isotretinoin?

If you miss any birth control pills, do not have sex for the rest of your cycle. You could get pregnant.

- If you miss 1 pill, take it as soon as you remember. Continue taking your other pills at the regular time. Call your doctor as soon as you realize it.
- If the whole day goes by before you realize you missed a pill, it is OK to take 2 pills together.
- **If you miss more than 2 days, you should call your doctor as soon as you realize it.** You are at a greater chance for pregnancy if you start a cycle late or miss taking pills during the first week of each cycle.

Reference ID: 3956479

Ask yourself:

1. If your 2 birth control forms are birth control pills and the diaphragm with spermicide, and you forgot to take 2 pills in a row, you should:

   A) Not worry because you are using a diaphragm with spermicide, too

   B) Not have sex and call your doctor because you do not have enough protection to keep from getting pregnant

   C) Take birth control pills 2 at a time until you catch up

2. You are talking to your doctor about having your second pregnancy test, so you can start isotretinoin. You have been on birth control pills for 1 month, and it is the second day of your period. Three days ago, you and your partner forgot to use a male latex condom when you had sex. You should:

   A) Have the pregnancy test anyway because it will tell you if you are pregnant

   B) Not worry because you have your period

   C)Tell the doctor you and your partner forgot to use a male latex condom once

   D) Not worry because you forgot before and never got pregnant

Answer key: page 38

Hormonal Skin Patch

The hormonal skin patch is a thin, plastic patch that you put on your skin. It releases female hormones into your body to protect against pregnancy.

Who should not use the hormonal skin patch?

You should not use the patch if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal skin patch?

You put a new patch on each week for 3 weeks. The fourth week is patch free, usually the time that you have a menstrual period. You place the hormonal skin patch where you can check it easily—on the upper outer arm, stomach, or upper body—but NOT on your breasts.

Reference ID: 3956479

Are you using the hormonal skin patch now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you have trouble remembering to change the patch each week? Has the patch ever come loose or fallen off and you did not immediately put on another one?
- Have you gained weight so that you weigh close to or more than 200 pounds?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using the hormonal skin patch, why do you think you would change to it?

Advantages

- It is not necessary to remember to take a daily pill.
- Many patients have more regular, lighter and shorter periods.

Disadvantages

- The patch does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If it becomes loose or falls off for more than 24 hours, you can get pregnant.
- If you leave the same patch on more than 1 week, you can get pregnant.
- Common side effects include breakthrough bleeding, nausea and vomiting, headaches and breast tenderness.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.
- Possible increased risk of blood clots. Please discuss this with your doctor.

Hormonal Vaginal Ring

The hormonal vaginal ring is a small flexible ring that you put into your vagina once a month. It releases female hormones into your body and works like birth control pills.

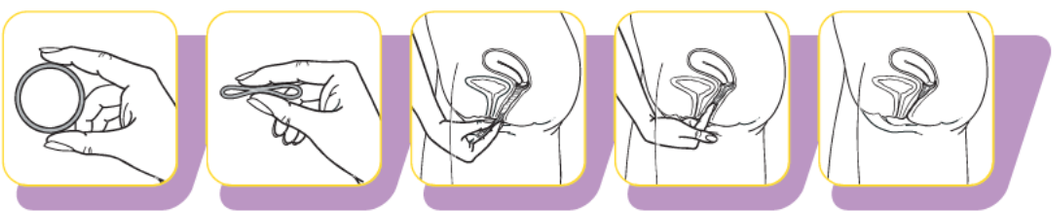
Who should not use the hormonal vaginal ring?

You should not use the hormonal vaginal ring if you:

- Smoke
- Had blood clots or breast cancer
- Have a history of heart disease, liver problems, high blood pressure, or diabetes
- Are pregnant or nursing

How do I use the hormonal vaginal ring?

You put a new ring in your vagina once every 4 weeks on the same day of the week. You leave it there for 3 weeks and then take it out. During the one-week break, you usually have a menstrual period. **If the ring slips out of the vagina during the 3-week period, you must replace it within 3 hours.**



Are you using the hormonal vaginal ring now?

If you are, is this going to be your primary form of birth control?
Before you decide, ask yourself:

- Do you have trouble remembering to remove the ring after 3 weeks?
- Has the ring ever slipped out and you did not notice?
- Do you have trouble inserting the ring?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using a hormonal vaginal ring, why do you think you would change to it?

Reference ID: 3956479

Advantages

- It is not necessary to remember to take a daily pill.
- It does not need to be fitted by a doctor.
- Many female patients have more regular, lighter, and shorter menstrual periods.
- Your ability to have children returns quickly after stopping the ring.

Disadvantages

- The ring does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- You cannot use it with a diaphragm or cervical cap.
- Some medicines for a vaginal yeast infection increase the level of hormones released into the blood.
- You may have trouble inserting the ring.
- Pregnancy can happen if:
  - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
  - The ring slips out of the vagina and you do not replace it within 3 hours
  - The ring does not stay in the vagina for 3 weeks
  - You leave the ring in the vagina for more than 3 weeks
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.

Hormonal Shots—Single Hormone

Single hormonal shots use a progestin (a female hormone) to prevent pregnancy. They keep you from releasing eggs, keep eggs from growing in the uterus, and make it harder for sperm to get to an egg.

Who should not take single hormonal shots?

You should not take single hormonal shots if you have any unexplained vaginal bleeding, have or had breast cancer, have liver problems or are pregnant.

How do I take single hormonal shots?

Your dermatologist, gynecologist, or family doctor can give you a shot in your arm, belly, or buttocks once every 12 weeks.

Reference ID: 3956479

Are you taking single hormonal shots now?

- If yes, is this going to be your primary form of birth control? How often do you miss shots?
- If you are not getting single hormonal shots, why do you think you would change to them?

Advantages

- A single shot works for 12 weeks at a time.
- There is no daily pill to take.
- You can use it if you cannot take the hormone estrogen.

Disadvantages

- Single hormonal shots do not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- They may cause thinning or loss of bone and should not be used for more than 2 years.
- They may cause irregular bleeding.
- If you are planning to get pregnant AFTER you finish your isotretinoin treatment, it may take up to 18 months to get pregnant after you stop getting single hormonal shots.

How soon does the single hormonal shot start to work?

If you get the shot within the first 5 days of your menstrual flow, the protection against pregnancy begins right away.

Hormonal Intrauterine Device

The hormonal IUD is a small piece of plastic your doctor puts into your uterus. The hormonal IUD has a progestin (female hormone) that keeps you from releasing eggs and slows down sperm.

Who should not use a hormonal IUD?

Some of the reasons women should not use the hormonal IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; problems with your immune system; leukemia; AIDS; IV drug abuse; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus.

Reference ID: 3956479

How do I use a hormonal IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The hormonal IUD can stay in place for up to 5 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Do you have a hormonal IUD now?

If you do, is this going to be your primary form of birth control? First, ask yourself these questions:

- Is the IUD in place? Can you feel the string?
- When did you last have it checked by your clinician? It needs to be checked within 3 months after you had it inserted.
- If you are not using a hormonal IUD, why do you think you would change to it?

Advantages

- It is a good choice for long-term birth control (5 years), and you may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps and heavy and longer menstrual periods for the first few months after it is placed, and increased chance of infection.
- Your body may push out the IUD. This can happen without your knowing it. This occurs mostly during a woman's menstrual period.
- You must check for the strings after each menstrual period to make sure the IUD is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Reference ID: 3956479

Ask yourself:

1. You have an IUD inserted as your choice for a primary form of birth control. Which of the following can you use as a second form?

   A) Male latex condoms with or without spermicide

   B) Hormonal shots

   C) Cervical cap without spermicide

   D) Diaphragm with spermicide

   E) Mini-pills (e.g., progesterone-only birth control pills)

   F) All of the above

Answer key: page 38

Hormonal Implants (Under-The-Skin)

Implantable birth control is a plastic rod(s), the size of a matchstick that is put under the skin in the upper arm by a healthcare provider in the office. It is effective for up to three years.

Who should not use

You should not use implantable birth control if you:

- Are pregnant
- Have or have had a current or past history of clots
- Have or have had liver disease
- Have or have had breast cancer
- Are allergic to anything in the implant

How do I use

The implant is put under the skin by a healthcare provider in the office. It generally cannot be seen once under the skin and once in, is effective for up to 3 years. It can be removed at any time by a procedure done by the healthcare provider in the office.

Advantages

- The rod works for up to 3 years
- There is no daily pill to take
- You can use it if you cannot take the hormone estrogen
- Your ability to have children may return quickly after removing the implant

Disadvantages

- Implant does not protect against STIs (sexually transmitted infections) or HIV (AIDS)
- May cause irregular and unpredictable bleeding
- Other side effects can include headache, acne, cramping and emotional changes

Reference ID: 3956479

- There can be side effects related to putting in the implant such as swelling, redness, pain, bruising, scarring, or infection
- There can be side effects related to removing the rod including a broken rod, or scar tissue making removal more difficult
- Rarely, it can be difficult or impossible to remove which may result in having to go to the operating room
- If you get pregnant, the chance of an ectopic pregnancy (a pregnancy not in your womb) is higher
- Ovarian cysts can occur
- May be less effective in women who are overweight or have liver problems –discuss this with your doctor
- Isotretinoin, antibiotics, and St. John's Wort may make the implant less effective

How soon does the implant work?

Discuss this with your healthcare provider.

Please make sure you can feel the implant rod under your skin after placement. If you cannot feel it, please do not start isotretinoin or have sexual intercourse until you talk to your healthcare provider.

Non-hormonal Intrauterine Device (Copper T IUD)

The Copper T IUD is a thin piece of plastic covered with the metal copper. It prevents pregnancy by slowing sperm down and keeping sperm from getting to the egg.

Who should not use the Copper T IUD?

Some of the reasons you should not use the Copper T IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus. You cannot use this IUD if you are allergic to copper or have Wilson's disease.

How do I use the Copper T IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The Copper T IUD can stay in place for up to 10 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Reference ID: 3956479

Advantages

- You can use it if you cannot take hormones.
- It is a good choice for long-term birth control (10 years).
- You may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STIs (sexually transmitted infections) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Side effects may include cramps, heavy and longer menstrual periods.
- Your body may push out the IUD. This can happen without you knowing it. This occurs mostly during your menstrual period.
- You must check for the string to make sure it is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.

Tubal Sterilization (Tying Your Tubes)

Tubal sterilization (tying your tubes) is an operation that closes the tubes from the ovaries to the uterus so that the sperm cannot get through to the egg. Female sterilization may be accomplished using a variety of techniques. They are all considered to be very effective, virtually permanent methods of pregnancy prevention and, with the exception of hysteroscopic tubal sterilization, are immediately effective. Hysteroscopic tubal sterilizations are not effective immediately and require that a test be done in three months to confirm that the tubes are blocked. For the purposes of the iPLEDGE Program, hysteroscopic tubal sterilization is not considered an effective primary method of birth control unless the confirmation test has been performed.

Who should not have a tubal sterilization?

- You should not have a tubal sterilization if you ever want to get pregnant, at any time now or in the future.
- If you have already had a tubal sterilization, this is your primary form of birth control while taking isotretinoin. You must also choose either a secondary form of birth control or another primary form.
- If you are thinking about tubal sterilization, here is some information

Advantages

- It is very effective birth control.
- It works immediately after the surgery, with the exception of hysteroscopic tubal sterilization which requires that a test be done in three months to confirm that the tubes are blocked.

Disadvantages

- Tubal sterilization does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If you want to have a child later, it is very difficult to re-open the tubes.
- It is surgery. You would need to have an operation.
- It increases the chance of ectopic pregnancy (pregnancy in the tubes) if sperm manage to get through the blocked tubes.

Partner's Vasectomy

A vasectomy is an operation that closes off the tubes that carry a man's sperm. The man's fluid should not have sperm in it after a vasectomy. If a man has sex before his doctor says his fluid has no sperm, the woman could get pregnant.

- If you have *only 1* partner *and* he has had a vasectomy, this can be your primary form of birth control while taking isotretinoin. You must also choose a second form of birth control. It is strongly recommended that you choose another primary form to give you very effective protection against getting pregnant.

If your partner is thinking about a vasectomy, here is some information about this very effective, but permanent, means of birth control.

Advantages

- It is very effective birth control.

Disadvantages

- A vasectomy does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- If a male wants a child later, it is very difficult to open the tubes again.
- A vasectomy requires minor surgery.

Ask yourself:

- Is this my only sexual partner?

If you said no or if you are not sure, you cannot choose vasectomy as your primary form of birth control.

Reference ID: 3956479

SECONDARY FORMS OF BIRTH CONTROL

Secondary forms of birth control do not adequately protect against pregnancy if they are the only form used. However, they greatly increase your protection against getting pregnant if you use them along with a primary form every time you have sex. Effective secondary forms of birth control forms include barrier forms (male latex condoms, diaphragms, and cervical caps) and other forms (vaginal sponge). The diaphragm and cervical cap must always be used with a spermicide, and the male latex condom can be used with or without spermicide. The vaginal sponge contains spermicide. If a secondary form is your second form of birth control, you must use it every time you have sex with a male. The female condom is not an effective secondary form for the iPLEDGE Program.

Always use a spermicide with diaphragms and cervical caps.

Ask your doctor, gynecologist, or family doctor to show you how to use secondary forms. Be sure you know how to use them correctly.

Make sure you know exactly how to use these forms of birth control. Know what mistakes people make with secondary forms. These mistakes can get you pregnant.

Spermicides

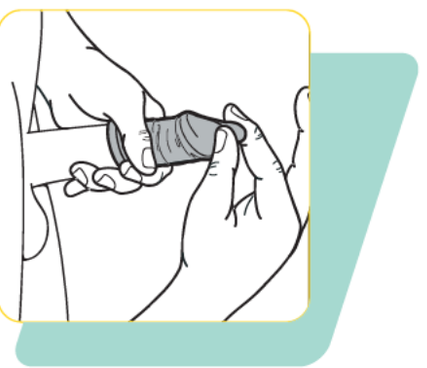
Spermicides come in several forms—creams, jellies, foams, and suppositories. You use spermicide 10 to 30 minutes before you have sex—each and every time—whenever the male comes in or near the female patient's vagina. Your dermatologist, gynecologist, family doctor, or birth control counselor can tell you how to use spermicides with your secondary barrier form.

Some people are allergic to spermicides. If you cannot use a spermicide, you must use 2 primary forms of birth control together, or a primary form with a male latex condom as your second form.

Male Latex Condom With or Without Spermicide

What is a male latex condom?

The male latex condom, also called a "rubber," is a thin cover put on the male's penis that traps sperm. You can use them with or without a spermicide .



How does my partner use it?

The male latex condom is unrolled on a male's erect penis as soon as he gets an erection. Waiting too long lets sperm leak out!

You can use a male latex condom with or without spermicide.

A male latex condom is good for 1 time only. Do not let your partner try to use it more than once. Oils like petroleum jelly or baby oil can ruin a male latex condom. Safe lubricants include anything made with a water-based gel such as KY Jelly®.

Make sure the male latex condom stays on during sex. If it tears or comes off, call your doctor about emergency birth control.

Choosing a male latex condom as your secondary form

If you choose male latex condoms as a secondary form, your partner must be willing to use a male latex condom each and every time you have sex. Ask yourself:

- Does your sexual partner use a latex condom? Does he have a problem with using a latex condom each time you have sex?
- Does anyone ever force you to have sex if you do not want to?
- Have you and your partner ever forgotten to use latex condoms even when you had meant to?
- Have you ever had sex after drinking when you had not planned to?

  Alcohol and drugs can affect your judgment and decisions about having sex.

Male latex condoms may not be the best secondary form for you to choose if:

- Your partner does not want to use them
- You do not like to interrupt sex to let your partner put on a male latex condom
- You have had sex when you did not plan to and did not use birth control

You may want to choose a form you can control or one that you can insert before having sex.

Advantages

- Male latex condoms *do* protect against STIs (sexually transmitted infections) and HIV (AIDS).
- Male latex condoms are easy to buy, and no doctor's appointment or pelvic exam is needed.
- It is easy to tell when it breaks or slips.

Disadvantages

- Males and females can have a latex allergy.
- Male latex condoms can break or slip during sex.
- Many males do not like or want to use them. Your partner has to be committed to using male latex condoms. You are not in control of this birth control form.
- You must remember to use them every time.
- You must interrupt sex play to put on a male latex condom.

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How soon does a male latex condom work?

It works as soon as the male puts it on his erect penis.

Ask yourself:

- Will your partner actually use the latex condom?
- Did you talk with him about it?
- Did he agree?

1. Your partner says he is tired of using latex condoms and asks if he can skip it once in a while. Hormonal shots are your primary form of birth control. You should:

   A) Agree to let him just use a condom every other time you have sex

   B) Tell him to use latex condoms until you get a diaphragm to use

   C)Tell him that you will not have sex with him unless he uses a latex condom

   D) Not worry because you have not gotten pregnant yet

Answer key: page 38

Diaphragm And Spermicide

What is a diaphragm?

The diaphragm is a shallow latex cup edged with a flexible ring. It covers your cervix and keeps sperm from getting into your uterus. Your gynecologist or family doctor can fit you with one.

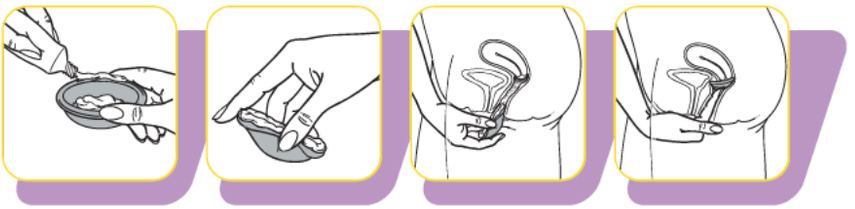
Who should not use the diaphragm?

You should not use a diaphragm if you have an allergy to latex or silicone, difficulty putting the diaphragm in, weak vaginal muscles, a history of bladder infections or toxic shock, or had a recent abortion.

Reference ID: 3956479

How do I use a diaphragm?

You bend the flexible ring and insert the diaphragm into your vagina. The back rim rests below and behind the cervix. The front rim is tucked behind your pubic bone. Before you insert it, you put spermicide in the center of the cup and around the ring.



You can put your diaphragm into the vagina up to 6 hours before sex. You have to leave it in place for at least 6 hours after you have sex. You must put spermicide in the vagina if you have sex again during this time. You should not leave it in for more than 24 hours at a time.

Choosing a diaphragm as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using diaphragms. If you are in one of these 2 groups, talk with your dermatologist, gynecologist, family doctor, or birth control counselor about whether the diaphragm is right for you.

Have you ever used a diaphragm? What do you like or dislike about the diaphragm?

- Do you find it easy to put it in?
- Have you been using spermicide with the diaphragm?
- Do you find it easy to remember to use it?
- Have you had your diaphragm checked by your gynecologist in the last 2 years to see if it still fits? You must have your diaphragm checked every 2 years, after a gain or loss of 10 pounds, OR after childbirth or an abortion.

If you answered yes to these questions, the diaphragm may be a good secondary form for you.

If you answered no to any of these questions, you should think about another secondary form.

Advantages

- You can easily carry a diaphragm with you and control its use.
- It is immediately effective.
- There are no hormones.
- You do not have to interrupt sex play—it can be inserted before sex.
- You can use it during your menstrual period.

Reference ID: 3956479

Disadvantages

- A diaphragm does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it hard to insert.
- You must put spermicide in your vagina if you have sex again.
- It can get pushed out of place during sex.
- It requires a prescription and pelvic exam. A diaphragm lasts about 1 to 2 years.
- You must check it for holes and tears and clean it after sex.

How soon does a diaphragm work?

It works as soon as spermicide is applied and you put it in correctly.

Cervical Cap And Spermicide

What is the cervical cap?

The cervical cap is a small latex or rubber cup. You use it with spermicide. It covers your cervix so that sperm cannot get in your uterus. It must fit perfectly to work. Your gynecologist or family doctor can fit you for one.

Who should not use a cervical cap?

You should not use a cervical cap if you have an allergy to latex or rubber, a history of pelvic infections, abnormal Pap tests, or Toxic Shock Syndrome (TSS).

How do I use a cervical cap?

The cap is filled one-third full with spermicide. You squeeze it as you put it in your vagina. You press it onto the cervix to cover it completely. You can put the cap in the vagina right before sex, but it stays better if you put it in place 30 minutes before sex. You have to leave it in place for at least 6 hours after you have sex. You can leave in place up to 48 hours.

The cervical cap is made of latex. Never use it with an oil-based lubricant like petroleum jelly. This will destroy the cap.

Reference ID: 3956479

What is the difference between a diaphragm and a cervical cap?

The cervical cap is a little harder to learn how to use. With a cervical cap, there is no need to insert extra spermicide if you have sex again. You can also leave the cap in place for a longer time—48 hours instead of 24 hours. You cannot use the cervical cap if there is any vaginal bleeding, such as during your menstrual period.

Choosing the cervical cap as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using the cervical cap. If you are in one of these 2 groups, talk with your gynecologist or family doctor about whether the cervical cap is right for you.

Have you ever used a cervical cap? What do you like or dislike about it?

- Do you find it easy to put in?
- Have you been using spermicide with the cervical cap?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the cervical cap may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Advantages

- You can easily carry a cervical cap with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance.

Disadvantages

- A cervical cap does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- Some female patients have an allergy to latex.
- Some female patients find it harder to insert than a diaphragm.
- You cannot use it during your menstrual period.
- You need a prescription and a pelvic examination to fit a cervical cap.
- A cap lasts about 1 year.
- You must check it for holes and tears and clean it after sex.

Reference ID: 3956479

Vaginal Sponge

What is the vaginal sponge?

The vaginal sponge is a soft foam disc or pillow containing 1 gram of the spermicide nonoxynol-9. Inserting the sponge puts spermicide in your vagina and keeps it there during sex. You insert it in the vagina so it sits over your cervix. It has a string loop attached for easy removal.

Who should not use a vaginal sponge?

Female patients who are allergic to the spermicide nonoxynol-9 should not use the vaginal sponge.

How do I use the vaginal sponge?

First, wash your hands. Wet the sponge thoroughly with clean tap water. Squeeze the sponge gently several times until it is foamy. This releases the spermicide. Pinch the sides of the sponge together. Be sure the string loop is on the underside of the sponge. Squat or sit down, bend your wrist, and push the sponge gently up into your vagina as far as it will go. Check the position of the sponge to make sure the sponge covers your cervix.

How do I take the sponge out?

Wait at least 6 hours after your last sexual activity before taking the sponge out. You can leave it in place for up to 30 hours. You do not need more spermicide if you have sex more than once during that time. To take the sponge out, you need to catch the string loop and gently pull on it.

Choosing the vaginal sponge as your secondary form

Have you ever used a vaginal sponge? What do you like or dislike about it?

- Do you find it easy to put in? Easy to take out?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the vaginal sponge may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Reference ID: 3956479

Advantages

- You can easily carry a vaginal sponge with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance and is effective for up to 30 hours.
- No fitting is needed; you can buy it over the counter.
- It is comfortable and easy to use.

Disadvantages

- The vaginal sponge does not protect against STIs (sexually transmitted infections) or HIV (AIDS).
- It is not as effective in female patients who have had children.

EMERGENCY BIRTH CONTROL (Emergency Contraception)

Emergency birth control is also called "after sex" or "morning after" birth control. It can prevent pregnancy after sex without adequate protection. Emergency birth control prevents release of the egg, joining of the sperm and the egg, or implanting of the egg in the uterus. Emergency birth control is only for a female patient who is sure she is not already pregnant.

There are 2 forms of emergency birth control:

1. Emergency Contraceptive Pills (ECPs)—some must be used within 3 days, others must be used within 5 days of having sex without adequate protection. The sooner you take ECP, the more likely it is to work. It is best if ECP begins within 12 hours after you have sex without adequate protection. The pills may give you severe nausea. Ask your doctor for something to help with the nausea if you need this treatment. ECP does not take the place of your usual birth control, nor does it continue to prevent pregnancy during the rest of your menstrual cycle.
2. Putting in an IUD—used within 5 days. You need to have the IUD inserted within 5 days of having sex without adequate protection.

When would I need emergency birth control?

Call your doctor or gynecologist about emergency birth control if you had sex without adequate protection, such as:

- You forgot to take 2 or more birth control pills and had sex.
- You had sex without using a second form of birth control.
- You were late for your birth control hormonal shot and had sex.
- Your partner's condom broke or slipped off.
- Your diaphragm or cervical cap slipped out of place or ripped during sex.

Reference ID: 3956479

Emergency birth control is meant only for emergencies. It does NOT take the place of your usual 2 forms of birth control and it will not protect against sexually transmitted infections (STIs). Emergency birth control is not to be used instead of regular birth control and it does not work if you are already pregnant.

Where can I get emergency birth control?

You can get emergency birth control from:

- Private doctors or nurse practitioners
- Planned Parenthood
- Women's health centers
- Many hospital emergency rooms (unless they are owned by organizations opposing birth control)
- Available over-the-counter

Whom should I call if I cannot find emergency birth control?

Call the private toll-free Emergency Contraception Hotline at 1-888-NOT-2-LATE (1- 888-668-2528). They will ask for your city or ZIP code to help you find emergency birth control near you.

Ask yourself:

1. The right way to use emergency birth control is:

A) As a second form of birth control

B) If you find a tear in your cervical cap after sex

C)If you missed several birth control pills and then have sex

D) Only after a positive pregnancy test

Answer key: page 38.

REASONS FEMALE PATIENTS GET PREGNANT

There are many reasons female patients get pregnant when they do not want to. You can avoid most of these.

- They did not avoid sex with a male when they were not using birth control.
- They used a birth control form that did not work very well.
- They did not use birth control all the time and every time they had sex.
- They did not use their birth control the right way.
- They had sex with a male partner when they were not expecting to.
- Their birth control form failed.

For most of the reasons, you can make a choice not to make the same mistake. It is very important that you are careful about birth control. Use your birth control as the iPLEDGE Program requires. Do not make mistakes that can lead to unexpected pregnancy.

SEPARATING THE MYTHS FROM THE FACTS

Myths are ideas that many people believe are true, but they are not true. You need to know the facts about sex, birth control, and pregnancy to protect yourself.

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
You cannot get pregnant the first time you have sex.	You can get pregnant **any** time you have sex.
You cannot get pregnant if you "do it" standing up.	You can get pregnant in any position.
You will not get pregnant if you do not have an orgasm (come).	You can get pregnant any time you have sex regardless of whether or not you have an orgasm.
Douching keeps you from getting pregnant.	Douching does **not** prevent pregnancy.
You do not have to use something every time.	You should use birth control every time you have sex.
You will not get pregnant if it is the "safe time" of the month.	There is no safe time, even for female patients who are regular with their menstrual periods. Your body can change and you could get pregnant.
You will not get pregnant if he pulls out before he comes.	Even if he pulls out, he may leak sperm before he comes and you can get pregnant.
It is safe for me to have sex any time, unless I feel PMS changes or pain near my ovaries.	You can get pregnant any time you have sex, not just when you think you are ovulating (releasing an egg).
You cannot get pregnant if you have not had a menstrual period yet.	Your ovaries release an egg (ovulation) before your first menstrual period. You can get pregnant even the very first time this happens, if you have been having sex.
You cannot get pregnant if you have sex underwater.	You can get pregnant **anywhere** you have sex.

Reference ID: 3956479

MYTH—WHAT YOU HEAR	FACT—WHAT IS TRUE
My partner says he is sterile (has no sperm) because he had mumps. He never got anyone else pregnant, so I will not get pregnant.	Mumps rarely causes sterility (no sperm). You can get pregnant if you have sex with a man who has had mumps.
You cannot get pregnant if you miss only 1 birth control pill.	Birth control pills work best when you take them as prescribed. You can get pregnant if you miss even one pill, especially at the beginning of your pill cycle
Sexually active means you have to move during sex. If I do not move, I cannot get pregnant.	You can get pregnant any time you have sex, whether you move or lie still.
I am going through menopause and only get my menstrual period every couple of months.	You can get pregnant until you have missed your menstrual period for 1 year—12 months in a row.

You may have heard or read about something that is not listed here that you think might keep you from getting pregnant. Be sure to ask your dermatologist, gynecologist, or family doctor about any form that you cannot find in this book that you think, or have heard, will keep you from getting pregnant. You can only use the effective forms of birth control for the iPLEDGE Program.

SEX, ALCOHOL, AND DRUGS

You have seen this message many times before. Alcohol and drugs can make you unable to use good judgment. While you are taking isotretinoin and for 1 month after your last dose, you need to be able to remember to use 2 effective forms of birth control together each and every time you have sex with a male.

Do not let drugs or alcohol keep you from using your secondary form when you have sex. Use it the right way. You need to be in control of yourself so:

- You use your secondary form, OR you get your partner to use a male latex condom with or without spermicide
- You use a vaginal sponge, or a diaphragm or a cervical cap with spermicide

RECOGNIZING PREGNANCY

If you think you might be pregnant, stop isotretinoin and call your doctor right away. Here are some signs that you might be pregnant:

- You miss your menstrual period.
- You have nausea first thing in the morning.
- Your breasts feel really tender, like at the beginning of a menstrual period.
- The area around your nipples may look darker.
- You feel really tired and want to sleep.
- You feel you have to go to the bathroom a lot.
- You may have spotting of blood at the time of your menstrual period, but no real bleeding.

Ectopic (Tubal) Pregnancy

Sometimes a baby starts to grow outside the uterus. This is a serious problem. Call your doctor right away, if you have these signs:

- Sudden pain or severe cramping in your lower abdomen
- Bleeding or spotting with abdominal pain after you miss a menstrual period
- Fainting or dizziness lasting more than a few seconds

Pregnancy Testing

If you have any questions about whether you might be pregnant, talk with your doctor.

NOTES:

NOTES:

Birth Control Information

You can get information about birth control 24 hours a day, 7 days a week on the telephone. Call the toll-free number **1-866-495-0654** to learn about these subjects:

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

This telephone line is for education only. It does not take the place of talking with your doctor. He or she is the best source of information for you.

Answer Key To Birth Control Questions

Page 8:
- 1. B
- 2. A and D

Page 11:
- 1. B
- 2. B and C
- 3. A

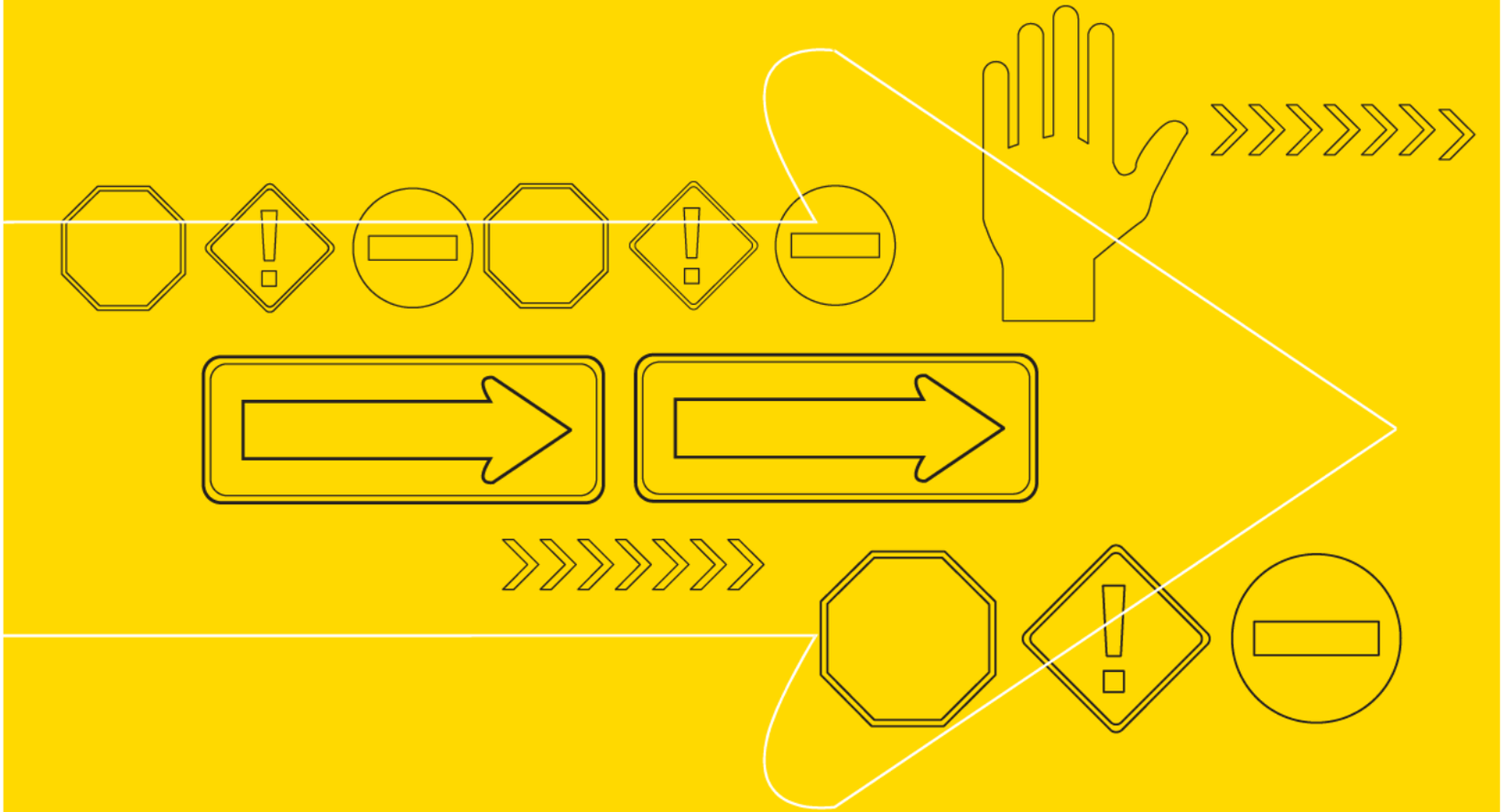
Page 14:
- 1. B
- 2. C

Page 20:
- 1. A and D

Page 26:
- 1. B and C

Page 32:
- 1. B and C

Reference ID: 3956479



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

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

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

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

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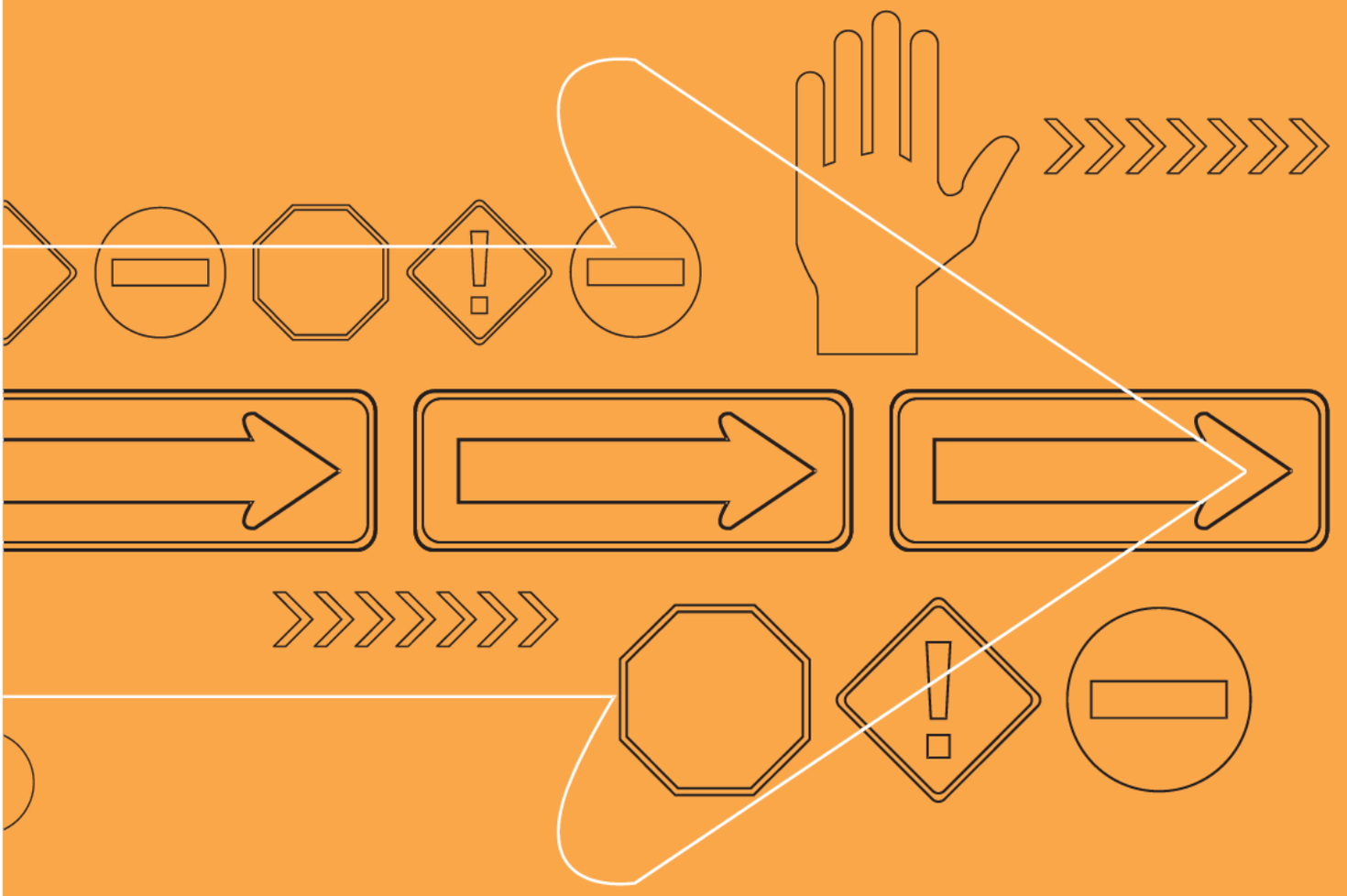
Reference ID: 3956479

Contraception Referral Form And Contraception Counseling Guide



- Referral form for contraception counseling and guide for counselors on effective forms of contraception

Reference ID: 3956479

Most Recent Modification: July 2016

The iPLEDGE Program

Contraception Referral Form And Contraception Counseling Guide

Referral form for contraception counseling and guide for counselors to effective forms of contraception

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

IMPORTANT NOTICE

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

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

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Reference ID: 3956479

Contraception Referral Form And Contraception Counseling Guide

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Contraception requirements 6

Unacceptable forms of contraception 8

Emergency contraception 9

Abstinence 9

Reporting a pregnancy 10

About This Referral Form

The Isotretinoin Contraception Referral Form, brought in to you by this patient, has been filled out in part by the prescriber. Please fill out the rest of the form at the conclusion of your counseling session and fax or mail the copy back to the prescriber, keeping a copy for your own records.

On the back of the referral form is a reimbursement form for contraceptive counseling services. The iPLEDGE Program provides reimbursement for 1 contraception counseling session for patients who have been prescribed isotretinoin. Please complete the form and fax it to 1-866-495-0660.

Reference ID: 3956479

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iPLEDGE–Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

ISOTRETINOIN CONTRACEPTION REFERRAL FORM

Prescriber: Complete for Patients Being Referred for Contraception Counseling

Patient_____, iPLEDGE Program ID#_____ is considering treatment with isotretinoin. I am referring her for counseling to help her choose her 2 forms of contraception before she receives her first prescription.

Please complete the Record of Contraception Counseling below and return this form to my office, via fax or mail.

She had a negative (serum/urine) pregnancy test on _____

Please review this *Contraception Counseling Guide* for details on the iPLEDGE Program contraception requirements.

Isotretinoin Prescriber's Name_____

Address _____

Telephone _____-_____-_____ Fax _____-_____-_____

Isotretinoin Prescriber's Signature _____

Date _____

RECORD OF CONTRACEPTION COUNSELING

Contraception Counselor: Complete Form and Fax or Mail Back to Isotretinoin Prescriber

I have provided the following for your patient _____

- ❑ Comprehensive contraception counseling
- ❑ Information about emergency contraception

The patient has:

- ❑ Not yet decided upon the forms of contraception she will use
- ❑ Chosen 2 forms of contraception
- ❑ Decided to abstain from any sexual contact with a male and is not planning to use 2 forms of contraception. I informed her that abstinence without using contraception is not recommended for the iPLEDGE Program for sexually active women.

Primary Form _____

Secondary or Second Primary Form_____

I have prescribed the selected contraception.

❑ Yes ❑ No (Please comment below)

I believe that this patient is fully committed to complying with the contraceptive requirements of the iPLEDGE Program.

❑ Yes ❑ No (Please comment below)

_____

Name_____

Address _____

Telephone _____

Specialty (circle one): OB-GYN Fam Prac IM RN LPN Other_____

Contraception Counselor's Signature _____

Date _____

Prescriber Copy-White **Contraception Counselor Copy-Yellow** **Patient Copy-Pink**

© 2007
PRE_FORM03 SEP15

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

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FAXABLE REIMBURSEMENT FORM

The Following Restrictions Apply:

Only consulting clinicians who provide initial pregnancy prevention counseling are eligible for reimbursement for such counseling. Other services provided during this visit are not eligible for reimbursement. The physician prescribing isotretinoin, or any other person working under the direct supervision of said physician, is not eligible for this reimbursement provision. The reimbursement fee is up to $150.00, which has been determined to be an average, usual, and customary reimbursement for service of this type. Information will be used only for reimbursement; the isotretinoin manufacturers will not use it for any other purpose.

Reimbursement For Pregnancy Prevention Counseling

To receive reimbursement for providing pregnancy prevention counseling to an isotretinoin patient, please answer the following questions, and sign, date, and send the completed form via fax to: 1-866-495-0660.

Contraception Counselor Name_____

Payee Name (if different than Contraceptive Counselor) _____

Office Telephone Number _____-_____-_____ Tax ID Number

Payee Address _____

City_____ State ____ ZIP _____

Name of Referring Physician _____

Office Telephone Number_____-_____-_____-_____

City_____ State ____ ZIP _____

Patient's Name _____

Patient's iPLEDGE Program ID Number _____

- ❑ I have provided pregnancy prevention counseling to this patient. I have mailed or faxed the record of pregnancy prevention counseling (on reverse side) to the isotretinoin prescriber.
- ❑ I am not the prescribing physician of isotretinoin to the patient referenced above, nor am I employed by said prescribing physician.
- ❑ I have not, and will not, bill or submit for reimbursement either directly or indirectly, under Medicaid, Medicare, or similar federal or state healthcare programs, or under any private insurance, HMO, or other healthcare benefit program for the pregnancy prevention counseling services described above.
- ❑ I attest that all of the above information is accurate and understand that I must check each box above to receive reimbursement.
- ❑ I have included a signed W-9 Form, or already have a W-9 form on file for payment from the iPLEDGE Program. A blank W-9 form and instructions for completion can be found at www.irs.gov

Signature _____ Date _____

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Reference ID: 3956479

CONTRACEPTION COUNSELING FOR ISOTRETINOIN PATIENTS

Isotretinoin is used to treat severe recalcitrant nodular acne; however, it is also a known human teratogen. Over one third of all babies exposed to isotretinoin *in utero* and carried to term have major birth defects.[1,2] The public health goal for isotretinoin is to eliminate fetal exposure by ensuring that no female starts isotretinoin therapy if pregnant and no female on isotretinoin therapy becomes pregnant. The US Food and Drug Administration has approved the iPLEDGE Program, an enhanced pregnancy risk management program for isotretinoin, to help achieve that end.

The contraception that a patient selects can have a dramatic effect on her chance of becoming pregnant. A patient using isotretinoin needs to select forms with low failure rates that she and/or her partner will use correctly each time they have intercourse.

Your Role

This patient is being referred to you because she has asked for counseling to help her comply with the contraception requirements of the iPLEDGE Program.

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

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

Please read this iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide completely before you begin your counseling session. It provides a pregnancy risk management context through which contraception choices for female patients taking isotretinoin can be viewed. It does not contain detailed information on the various forms of contraception.

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

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

COUNSELING GOALS

Ensure That The Patient:

- Understands the risk of having a child with significant birth defects from exposure to isotretinoin.
- Understands the need for using 2 forms of contraception together consistently and correctly and knows when to contact her prescriber for emergency contraception.
- Chooses the forms of contraception that will work best for her, that will provide her with the lowest practical failure rate, and that she and her partner will actually use. Adherence impacts the failure rate of hormonal combination oral contraceptives more strongly than other primary forms. (Please see "Hormonal Combination Oral Contraceptives As A Primary Form" on page 6.)
- Commits fully to not becoming pregnant and to using 2 forms of contraception simultaneously, consistently, and correctly. In previous isotretinoin risk management programs, patients understood the need for 2 forms of contraception; however, they did not comply, despite adequate information about the risk to the fetus. If, after counseling, the patient recognizes she will not be able to commit fully, encourage her to not take isotretinoin or do not prescribe.
- Is able and willing to maintain abstinence, if that is her choice after counseling. If a patient who has ever been sexually active chooses abstinence, and you believe that she will not be able to maintain abstinence and will not use contraception, encourage her to not take isotretinoin.

Counseling younger teens

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

- The birth control forms that are effective as primary and secondary forms.
- Why it is important to use 2 forms of birth control. Younger teens may need more emphasis on this point to fully understand it and comply.
- Emergency contraception. Younger teens may need more explanation from you about the need to take immediate action if they had unprotected sex.

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

CONTRACEPTION REQUIREMENTS

Using 2 Forms Of Contraception Provides More Protection

Use of 2 forms of contraception (at least one of which is a primary form) simultaneously substantially reduces the chances that a female will become pregnant over the risk of pregnancy with either form alone.

In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin.[3] Because of this possibility and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE Program requires the additional protection of a second form of contraception.

Selecting An Effective Primary Form Of Contraception

Table 1 on the next page lists, by typical use failure rate, the primary forms of contraception acceptable in the iPLEDGE Program. The single most important decision in contraception for the iPLEDGE Program is selecting a primary form with a very low failure rate that the patient can and will use as perfectly as possible. Other important factors to consider in selecting a primary form include side effects, contraindications, and willingness and ability to use it perfectly. All of these factors influence compliance and the chance of unwanted pregnancy.

Hormonal Combination Oral Contraceptives As A Primary Form

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

Other contraception not requiring daily choices may be a better choice for a patient who does not take oral contraceptives perfectly. For example, if such a patient chooses an IUD, she reduces her chances of becoming pregnant by up to approximately 90%.[3] It is critical that such a patient choose a form other than oral contraceptive agents.

Table 1: Primary Forms Of Contraception By Typical Use Failure Rate

	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	**Perfect Use**	**Typical Use**
Hormonal Implantable	0.05%	0.05%
Partner's Vasectomy	0.10%	0.15%
Hormonal IUD (LNg20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A)[b]	0.60%	0.80%
Hormonal Injectable (single)	0.30%	3.00%
Hormonal Transdermal Patch	0.30%	8.00%
Hormonal Vaginal Ring	0.30%	8.00%
Hormonal Combination Oral Contraceptives[b]	0.30%	8.00%

a Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al, eds *Contraceptive Technology.* Nineteenth Revised Edition, New York, NY: Ardent Media 2007

b The IUD Progesterone T and progestin-only "mini-pills" are not acceptable primary forms for the iPLEDGE program (See "Unacceptable Forms Of Contraception" on page 8)

Selecting An Effective Secondary Form Of Contraception

Table 2 lists the acceptable secondary forms of contraception in the iPLEDGE Program. There are 2 forms of secondary contraception: barrier and other. Barrier forms include the diaphragm and cervical cap (both of which must be used with spermicide) and the male latex condom (which can be used with or without spermicide). The other form is the vaginal sponge, which contains spermicide. The most important issue for a secondary form is whether it will be used each time the patient has intercourse (i.e., will it be in place when the first form fails). Failure rate with perfect use is of secondary importance.

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

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

Table 2: Secondary Forms Of Contraception Listed By Typical Use Failure Rate		
	Percentage of Women Experiencing an Unintended Pregnancy Within the First Year of Use[a]	
Form	**Perfect Use**	**Typical Use**
Barrier Forms		
Male Latex Condom[b]	2%	15%
Diaphragm[*]	6%	16%
Cervical Cap[d,*]	9%	20%
Other Forms		
Vaginal Sponge[c]	9%	16%

a Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al, eds *Contraceptive Technology* 19th Revised Edition, New York, NY: Ardent Media, 2007

b Female condoms are not acceptable for the iPLEDGE program (See "Unacceptable Forms Of Contraception" below) Failure rate for Male Latex Condom is for use without spermicide

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

d Adapted from Trussell J Contraceptive efficacy In: Hatcher RA, Trussell J, Stewart F, et al,eds *Contraceptive Technology*. 17th Edition, New York, NY: Irvington Publishers 1998

* Failure rates for Diaphragm and Cervical Cap include the use of spermicide

UNACCEPTABLE FORMS OF CONTRACEPTION

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

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

Patients currently using these forms of contraception must switch to effective forms of contraception. They must use 2 effective forms together (at least one of which must be a primary form) consistently and correctly for at least 1 month and have a negative pregnancy test before beginning isotretinoin.

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

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

EMERGENCY CONTRACEPTION

Review this section in *The iPLEDGE Program Birth Control Workbook* with the patient. She should know when to call her prescriber for possible emergency contraception. She should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms she selected.

ABSTINENCE

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

REFERENCES

1 Lammer EJ, Chen DT, Hoar RM, et al Retinoic acid embryopthy *N Engl J Med* 1985;313:837-841
2 Gideon K, Avner M, Shear N Generic isotretinoin: a new risk for unborn children *CMAJ* 2004;170:1567-1568
3 Isotretinoin Prescribing Information, 2005

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

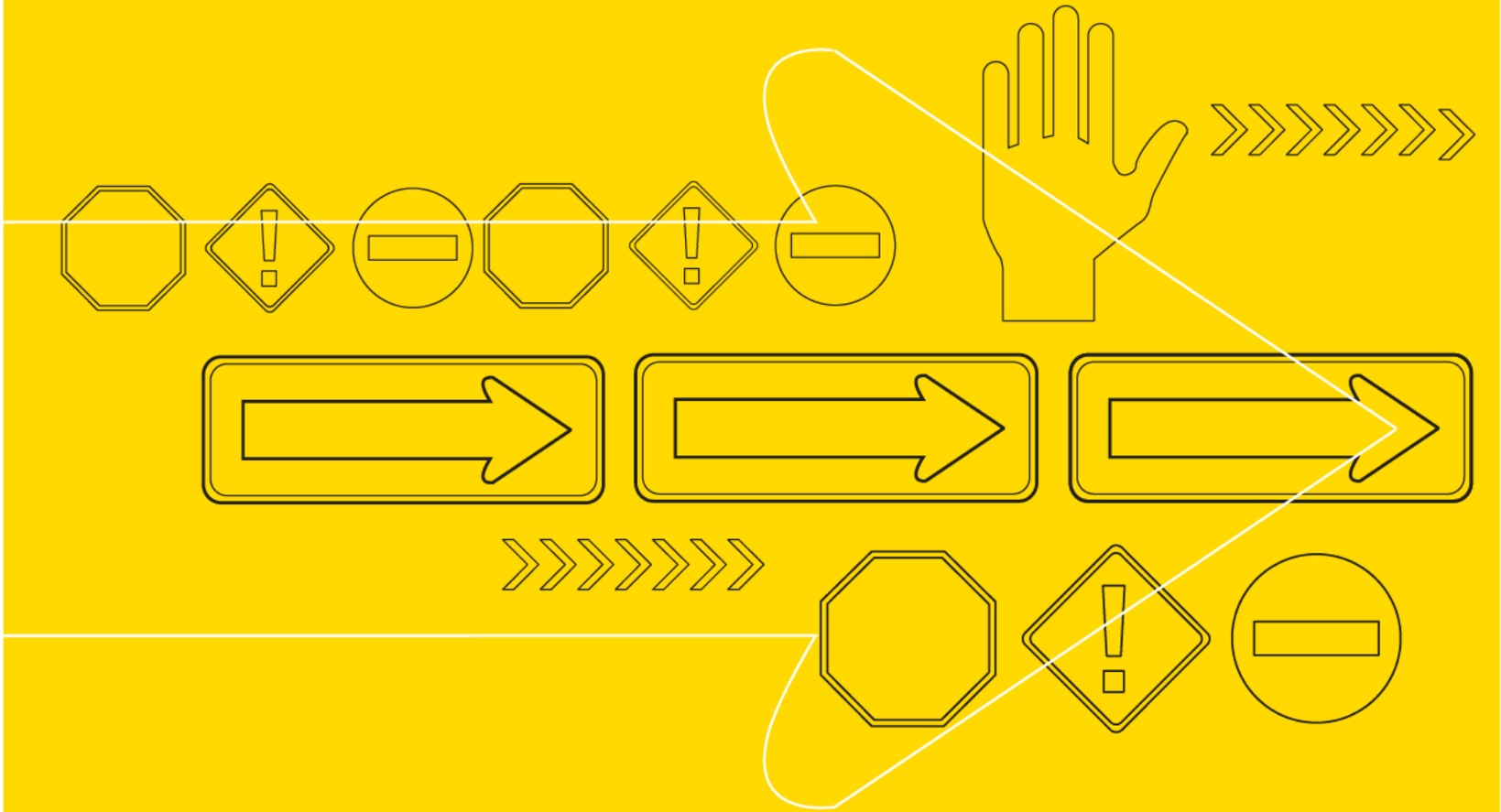
Reporting a Pregnancy

If you become aware of a pregnancy in a patient taking isotretinoin, please report the pregnancy to the iPLEDGE Program by calling **1-866-495-0654** and choosing the option to "Report a Pregnancy."

Please also remind any patient who is pregnant to contact the doctor who prescribed her isotretinoin.

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

Reference ID: 3956479



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

IMPORTANT NOTICE

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

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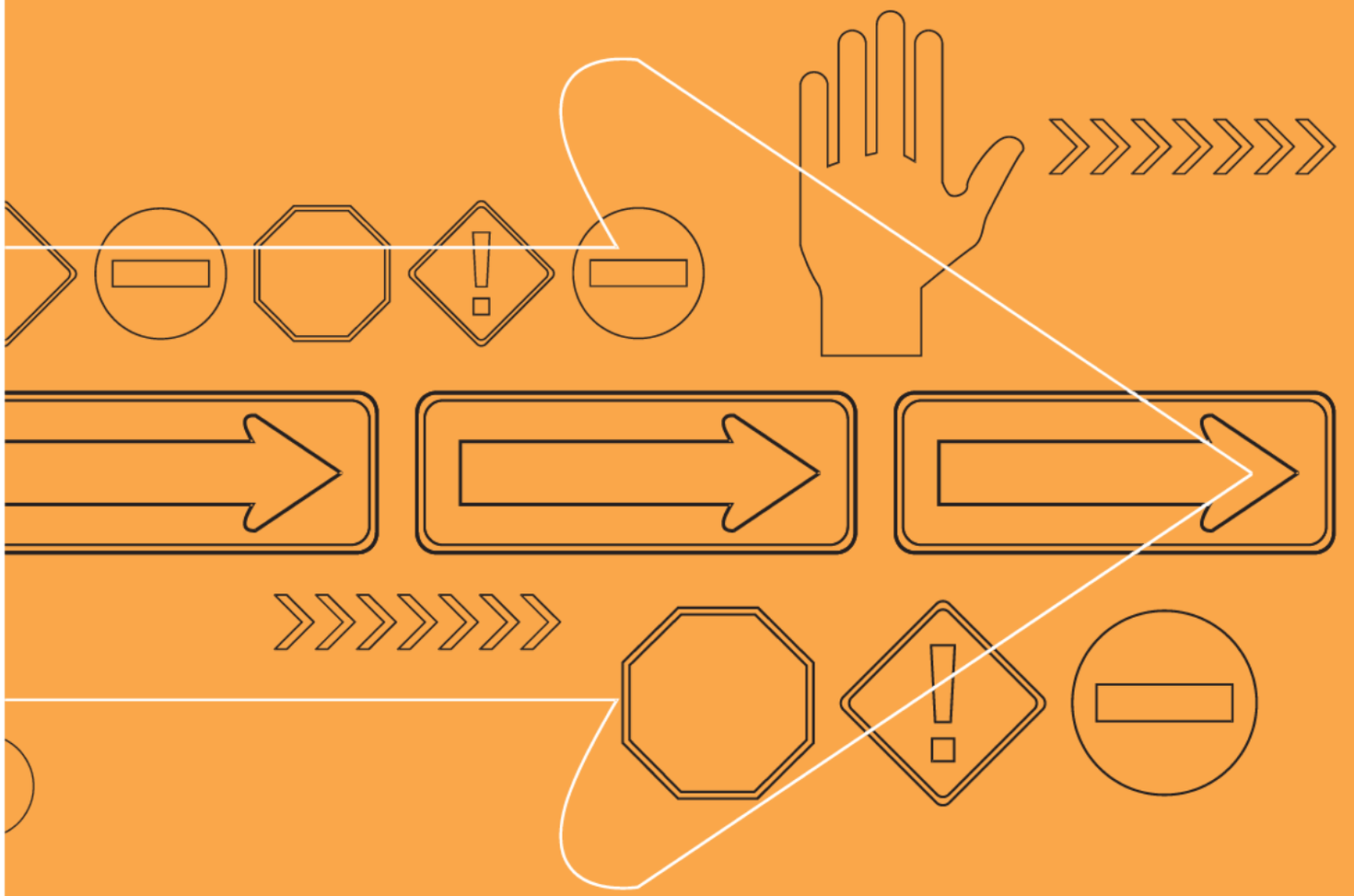
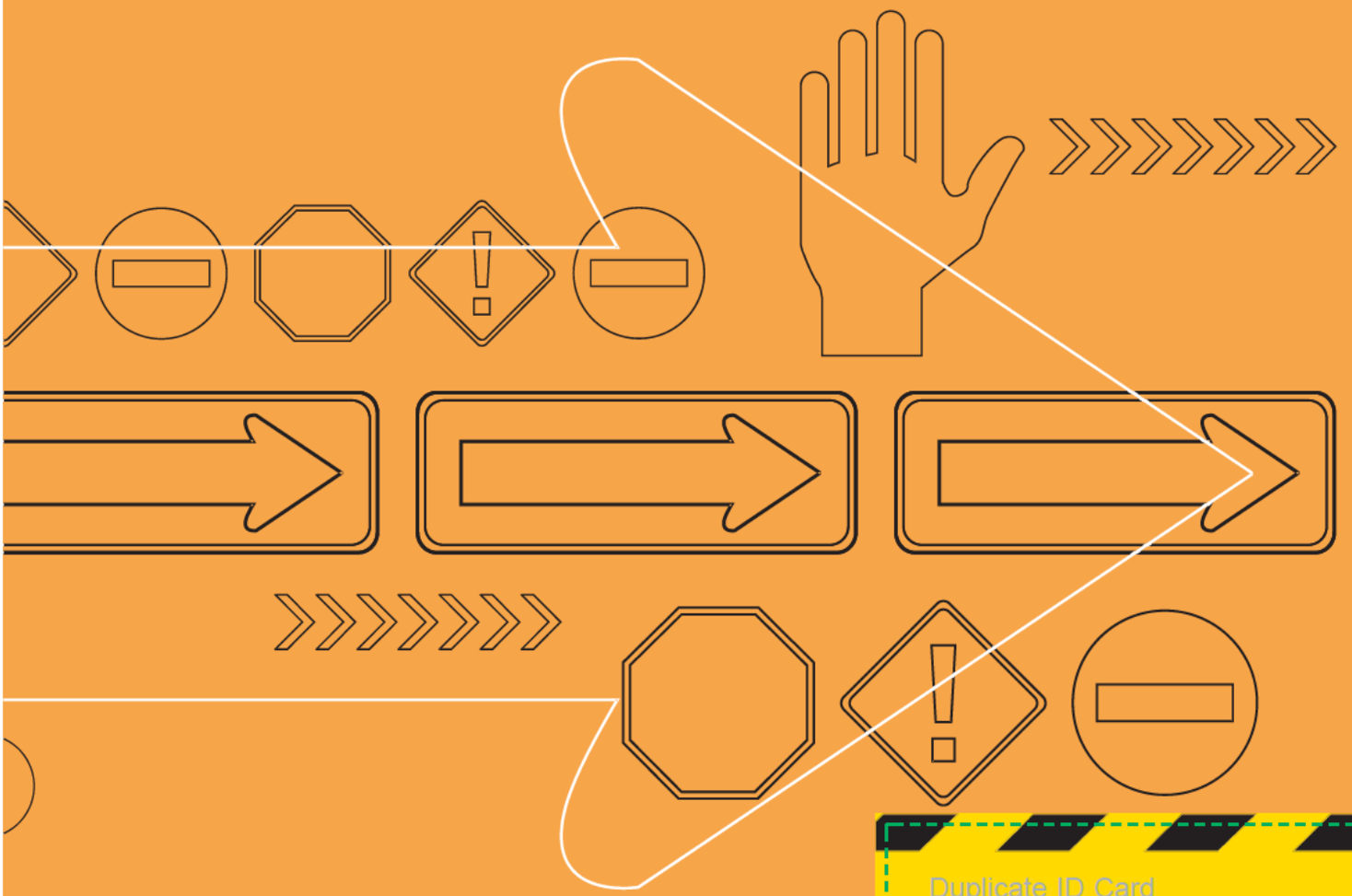
Patient Identification Card



› The card you need to take with you to doctor visits and to the pharmacy while on isotretinoin



Peel off sticker for patient's file

Duplicate ID Card

- Visit your doctor monthly
- Women who can get pregnant must:
  1. Have a monthly pregnancy test
  2. Complete monthly questions by web at www.ipledgeprogram.com or by calling 1-866-495-0654
- Take this card and your prescription to the pharmacy within your 7-day window
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

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iPLEDGE™ Committed to Pregnancy Prevention

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See reverse for important safety information

iPLEDGE™ Committed to Pregnancy Prevention

Reference ID: 3956479

Stop isotretinoin and call your doctor right away if you are pregnant. Stop isotretinoin and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- Start to feel sad or have crying spells
- Lose interest in activities you once enjoyed
- Sleep too much or have trouble sleeping
- Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- Have a change in your appetite or body weight
- Have trouble concentrating
- Withdraw from your friends or family
- Feel like you have no energy
- Have feelings of worthlessness or guilt
- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Start acting on dangerous impulses
- Start seeing or hearing things that are not real

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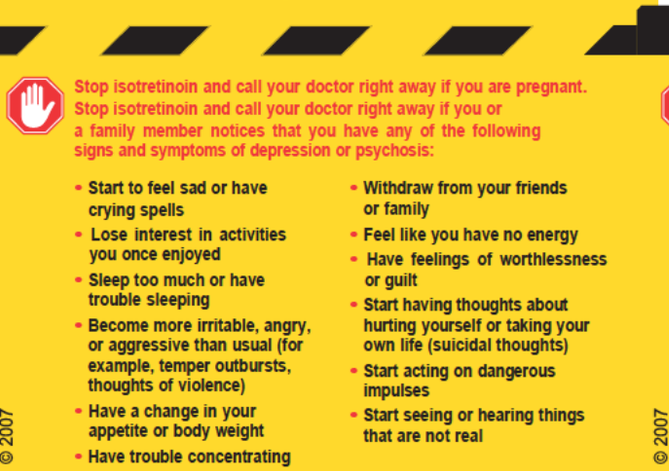

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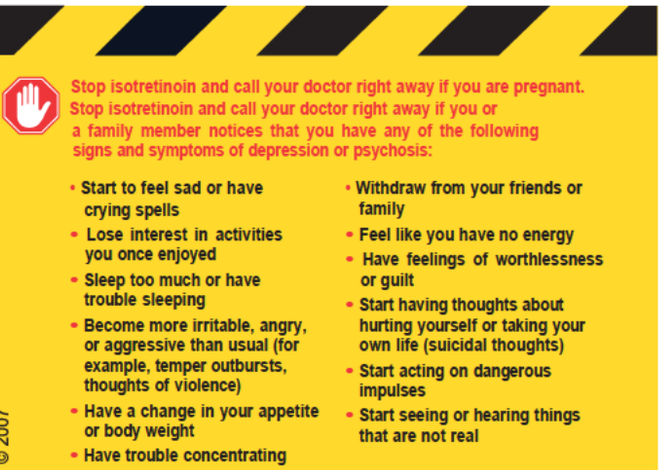

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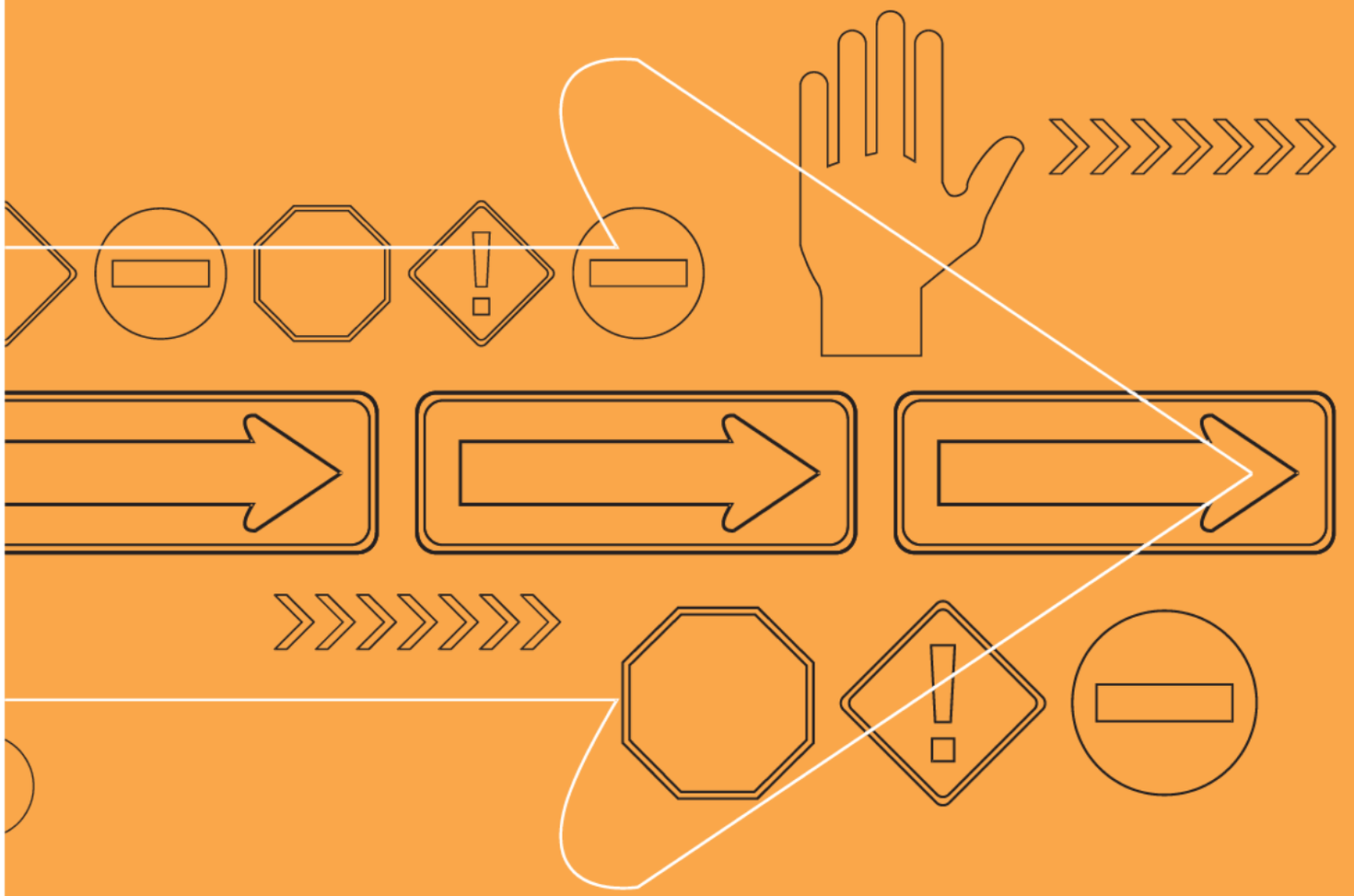
Reference ID: 3956479

Patient Information/Informed Consent



› Important forms you must sign before you begin taking isotretinoin

iPLEDGE–Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

Patient Information/Informed Consent (for all patients):

To be completed by patient (and parent or guardian if patient is under age 18) and signed by the doctor.

Read each item below and initial in the space provided if you understand each item and agree to follow your doctor's instructions. A parent or guardian of a patient under age 18 must also read and understand each item before signing the agreement.

Do not sign this agreement and do not take isotretinoin if there is anything that you do not understand about all the information you have received about using isotretinoin.

1. I, _____
(Patient's Name)
understand that isotretinoin is a medicine used to treat severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics. In severe nodular acne, many red, swollen, tender lumps form in the skin. If untreated, severe nodular acne can lead to permanent scars.
Initials: _____
2. My doctor has told me about my choices for treating my acne.
Initials: _____
3. I understand that there are serious side effects that may happen while I am taking isotretinoin. These have been explained to me. These side effects include serious birth defects in babies of pregnant patients. [Note: There is a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)].
Initials: _____
4. I understand that some patients, while taking isotretinoin or soon after stopping isotretinoin, have become depressed or developed other serious mental problems. Symptoms of depression include sad, "anxious" or empty mood, irritability, acting on dangerous impulses, anger, loss of pleasure or interest in social or sports activities, sleeping too much or too little, changes in weight or appetite, school or work performance going down, or trouble concentrating. Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent. No one knows if isotretinoin caused these behaviors or if they would have happened even if the person did not take isotretinoin. Some people have had other signs of depression while taking isotretinoin (see #7).
Initials: _____
5. Before I start taking isotretinoin, I agree to tell my doctor if I have ever had symptoms of depression (see #7), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems. Being psychotic means having a loss of contact with reality, such as hearing voices or seeing things that are not there.
Initials: _____
6. Before I start taking isotretinoin, I agree to tell my doctor if, to the best of my knowledge, anyone in my family has ever had symptoms of depression, been psychotic, attempted suicide, or had any other serious mental problems.
Initials: _____
7. Once I start taking isotretinoin, I agree to stop using isotretinoin and tell my doctor right away if any of the following signs and symptoms of depression or psychosis happen. I:
   - Start to feel sad or have crying spells
   - Lose interest in activities I once enjoyed
   - Sleep too much or have trouble sleeping
   - Become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
   - Have a change in my appetite or body weight
   - Have trouble concentrating
   - Withdraw from my friends or family
   - Feel like I have no energy
   - Have feelings of worthlessness or guilt
   - Start having thoughts about hurting myself or taking my own life (suicidal thoughts)
   - Start acting on dangerous impulses
   - Start seeing or hearing things that are not real

   Initials: _____
8. **I agree to return to see my doctor every month I take isotretinoin to get a new prescription for isotretinoin, to check my progress, and to check for signs of side effects.**
Initials: _____
9. Isotretinoin will be prescribed just for me — I will not share isotretinoin with other people because it may cause serious side effects, including birth defects.
Initials: _____
10. I will not give blood while taking isotretinoin or for 1 month after I stop taking isotretinoin. I understand that if someone who is pregnant gets my donated blood, her baby may be exposed to isotretinoin and may be born with serious birth defects.
Initials: _____
11. I have read *The iPLEDGE Program Patient Introductory Brochure* and other materials my provider provided me containing important safety information about isotretinoin. I understand all the information I received.
Initials: _____
12. My doctor and I have decided I should take isotretinoin. I understand that I must be qualified in the iPLEDGE Program to have my prescription filled each month. I understand that I can stop taking isotretinoin at any time. I agree to tell my doctor if I stop taking isotretinoin.
Initials: _____

I now allow my doctor _____ to begin my treatment with isotretinoin.

Patient Signature: _____ Date: _____

Parent/Guardian Signature (if under age 18): _____ Date: _____

Patient Name (print) _____

Patient Address _____ Telephone _____ – _____ – _____

I have:

- fully explained to the patient, _____, the nature and purpose of isotretinoin treatment, including its benefits and risks
- provided the patient the appropriate educational materials, *The iPLEDGE Program Patient Introductory Brochure* and asked the patient if he/she has any questions regarding his/her treatment with isotretinoin
- answered those questions to the best of my ability

Doctor Signature: _____ Date: _____

PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.

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PRE_FORM01_SEP15

Reference ID: 3956479

iPLEDGE™
Committed to Pregnancy Prevention

iPLEDGE–Committed to Pregnancy Prevention
P.O. Box 29094
Phoenix, AZ 85038

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

TO BE COMPLETED BY THE PATIENT (AND HER PARENT OR GUARDIAN* IF PATIENT IS UNDER AGE 18) AND SIGNED BY HER DOCTOR.

READ EACH ITEM BELOW AND INITIAL IN THE SPACE PROVIDED TO SHOW THAT YOU UNDERSTAND EACH ITEM AND AGREE TO FOLLOW YOUR DOCTOR'S INSTRUCTIONS. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

*A PARENT OR GUARDIAN OF A MINOR PATIENT (UNDER AGE 18) MUST ALSO READ AND INITIAL EACH ITEM BEFORE SIGNING THE CONSENT.

_____
(PAT ENTS NAME)

1. I UNDERSTAND THAT THERE IS A VERY HIGH CHANCE THAT MY UNBORN BABY COULD HAVE SEVERE BIRTH DEFECTS IF I AM PREGNANT OR BECOME PREGNANT WHILE TAKING ISOTRETINOIN. THIS CAN HAPPEN WITH ANY AMOUNT AND EVEN IF TAKEN FOR SHORT PERIODS OF TIME. THIS IS WHY I MUST NOT BE PREGNANT WHILE TAKING ISOTRETINOIN.
   NITIAL: _____
2. I UNDERSTAND THAT I MUST NOT GET PREGNANT 1 MONTH BEFORE, DURING THE ENTIRE TIME OF MY TREATMENT, AND FOR 1 MONTH AFTER THE END OF MY TREATMENT WITH ISOTRETINOIN.
   NITIAL: _____
3. I UNDERSTAND THAT I MUST AVOID SEXUAL INTERCOURSE COMPLETELY, OR I MUST USE 2 SEPARATE, EFFECTIVE FORMS OF BIRTH CONTROL (CONTRACEPTION) **at the same time**. THE ONLY EXCEPTIONS ARE IF I HAVE HAD SURGERY TO REMOVE THE UTERUS (A HYSTERECTOMY) OR BOTH OF MY OVARIES (BILATERAL OOPHORECTOMY), OR MY DOCTOR HAS MEDICALLY CONFIRMED THAT I AM POST-MENOPAUSAL.
   NITIAL: _____
4. I UNDERSTAND THAT HORMONAL BIRTH CONTROL PRODUCTS ARE AMONG THE MOST EFFECTIVE FORMS OF BIRTH CONTROL. COMBINATION BIRTH CONTROL PILLS AND OTHER HORMONAL PRODUCTS INCLUDE SKIN PATCHES, SHOTS, UNDER-THE-SKIN IMPLANTS, VAGINAL RINGS, AND INTRAUTERINE DEVICES (IUDS). ANY FORM OF BIRTH CONTROL CAN FAIL. THAT IS WHY I MUST USE 2 DIFFERENT BIRTH CONTROL METHODS AT THE SAME TIME, STARTING 1 MONTH BEFORE, DURING, AND FOR 1 MONTH AFTER STOPPING THERAPY EVERY TIME I HAVE SEXUAL INTERCOURSE, EVEN IF 1 OF THE METHODS I CHOOSE IS HORMONAL BIRTH CONTROL.
   NITIAL: _____
5. I UNDERSTAND THAT THE FOLLOWING ARE EFFECTIVE FORMS OF BIRTH CONTROL:

PRIMARY FORMS	SECONDARY FORMS
• TUBAL STER LIZATION (TYING YOUR TUBES) • PARTNER'S VASECTOMY • NTRAUTERINE DEVICE • **hormonal (combination birth control pills, skin patches, shots, under-the-skin) implants, or vaginal ring)**	*Barrier forms* • MALE LATEX CONDOM WITH OR WITHOUT SPERMIC DE • DIAPHRAGM WITH SPERMICIDE • CERVICAL CAP WITH SPERMICIDE *Others:* • VAGINAL SPONGE (CONTAINS SPERMICIDE)

   A DIAPHRAGM AND CERVICAL CAP MUST EACH BE USED WITH SPERMICIDE, A SPECIAL CREAM THAT KILLS SPERM

   I UNDERSTAND THAT AT LEAST 1 OF MY 2 FORMS OF BIRTH CONTROL MUST BE A PRIMARY METHOD.
   NITIAL: _____
6. I WILL TALK WITH MY DOCTOR ABOUT ANY MEDICINES INCLUDING HERBAL PRODUCTS I PLAN TO TAKE DURING MY ISOTRETINOIN TREATMENT BECAUSE HORMONAL BIRTH CONTROL METHODS MAY NOT WORK IF I AM TAKING CERTAIN MEDICINES OR HERBAL PRODUCTS.
   NITIAL: _____
7. I MAY RECEIVE A FREE BIRTH CONTROL COUNSELING SESSION FROM A DOCTOR OR OTHER FAMILY PLANNING EXPERT. MY ISOTRETINOIN DOCTOR CAN GIVE ME AN ISOTRETINOIN PATIENT REFERRAL FORM FOR THIS FREE CONSULTATION.
   NITIAL: _____
8. I MUST BEGIN USING THE BIRTH CONTROL METHODS I HAVE CHOSEN AS DESCRIBED ABOVE AT LEAST 1 MONTH BEFORE I START TAKING ISOTRETINOIN.
   INITIAL: _____
9. I CANNOT GET MY FIRST PRESCRIPTION FOR ISOTRETINOIN UNLESS MY DOCTOR HAS TOLD ME THAT I HAVE 2 NEGATIVE PREGNANCY TEST RESULTS. THE FIRST PREGNANCY TEST SHOULD BE DONE WHEN MY DOCTOR DECIDES TO PRESCRIBE ISOTRETINOIN. THE SECOND PREGNANCY TEST MUST BE DONE IN A LAB DURING THE FIRST 5 DAYS OF MY MENSTRUAL PERIOD RIGHT BEFORE STARTING ISOTRETINOIN THERAPY TREATMENT, OR AS INSTRUCTED BY MY DOCTOR. I WILL THEN HAVE 1 PREGNANCY TEST, IN A LAB:
   - EVERY MONTH DURING TREATMENT
   - AT THE END OF TREATMENT
   - AND 1 MONTH AFTER STOPPING TREATMENT

   I MUST NOT START TAKING ISOTRETINOIN UNTIL I AM SURE THAT I AM NOT PREGNANT, HAVE NEGATIVE RESULTS FROM 2 PREGNANCY TESTS, AND THE SECOND TEST HAS BEEN DONE IN A LAB.
   INITIAL: _____
10. I have read and understand the materials my doctor has provided to me, including *The iPLEDGE Program Guide for Isotretinoin for Female Patients Who Can Get Pregnant, The iPLEDGE Birth Control Workbook* and *The iPLEDGE Program Patient Introductory Brochure.*

    MY DOCTOR PROV DED ME AND ASKED ME TO WATCH A V DEO ABOUT B RTH CONTROL AND A VIDEO ABOUT BIRTH DEFECTS AND ISOTRETINOIN.

    I WAS TOLD ABOUT A PRIVATE COUNSELING LINE THAT I MAY CALL FOR MORE INFORMATION ABOUT BIRTH CONTROL. I HAVE RECEIVED INFORMATION ON EMERGENCY BIRTH CONTROL.
    INITIAL: _____
11. I MUST STOP TAKING ISOTRETINOIN RIGHT AWAY AND CALL MY DOCTOR IF I GET PREGNANT, MISS MY EXPECTED MENSTRUAL PERIOD, STOP USING BIRTH CONTROL, OR HAVE SEXUAL INTERCOURSE WITHOUT USING MY 2 BIRTH CONTROL METHODS AT ANY TIME.
    INITIAL: _____
12. MY DOCTOR PROVIDED ME INFORMATION ABOUT THE PURPOSE AND IMPORTANCE OF PROVIDING NFORMATION TO THE PLEDGE PROGRAM SHOULD I BECOME PREGNANT WH LE TAK NG ISOTRETINOIN OR WITHIN ONE MONTH OF THE LAST DOSE. I UNDERSTAND THAT IF I BECOME PREGNANT, INFORMATION ABOUT MY PREGNANCY, MY HEALTH, AND MY BABY'S HEALTH MAY BE SHARED WITH THE MAKERS OF ISOTRETINOIN, AUTHORIZED PARTIES WHO MAINTAIN THE IPLEDGE PROGRAM FOR THE MAKERS OF ISOTRETINOIN, AND GOVERNMENT HEALTH REGULATORY AUTHORITIES.
    INITIAL: _____
13. I UNDERSTAND THAT BEING QUALIFIED TO RECEIVE ISOTRETINOIN IN THE IPLEDGE PROGRAM MEANS THAT I:
    - HAVE HAD 2 NEGATIVE URINE OR BLOOD PREGNANCY TESTS BEFORE RECEIVING THE FIRST ISOTRETINOIN PRESCRIPTION. THE SECOND TEST MUST BE DONE IN A LAB. I MUST HAVE A NEGATIVE RESULT FROM A URINE OR BLOOD PREGNANCY TEST DONE IN A LAB REPEATED EACH MONTH BEFORE I RECEIVE ANOTHER ISOTRETINOIN PRESCRIPTION.
    - HAVE CHOSEN AND AGREED TO USE 2 FORMS OF EFFECTIVE BIRTH CONTROL AT THE SAME TIME. AT LEAST 1 METHOD MUST BE A PRIMARY FORM OF BIRTH CONTROL, **unless I have chosen never to have sexual contact with a male (abstinence)**, OR I HAVE UNDERGONE A HYSTERECTOMY. I MUST USE 2 FORMS OF BIRTH CONTROL FOR AT LEAST 1 MONTH BEFORE I START ISOTRETINOIN THERAPY, DURING THERAPY, AND FOR 1 MONTH AFTER STOPPING THERAPY. I MUST RECEIVE COUNSELING, REPEATED ON A MONTHLY BASIS, ABOUT BIRTH CONTROL AND BEHAVIORS ASSOCIATED WITH AN INCREASED RISK OF PREGNANCY.
    - HAVE SIGNED A PATIENT INFORMATION/INFORMED CONSENT ABOUT BIRTH DEFECTS (FOR FEMALE PATIENTS WHO CAN GET PREGNANT) THAT CONTAINS WARNINGS ABOUT THE CHANCE OF POSSIBLE BIRTH DEFECTS IF I AM PREGNANT OR BECOME PREGNANT AND MY UNBORN BABY IS EXPOSED TO ISOTRETINOIN.
    - HAVE INTERACTED WITH THE IPLEDGE PROGRAM BEFORE STARTING ISOTRETINOIN AND ON A MONTHLY BASIS TO ANSWER QUESTIONS ON THE PROGRAM REQUIREMENTS AND TO ENTER MY TWO CHOSEN FORMS OF BIRTH CONTROL.
    INITIAL: _____

My doctor has answered all my questions about isotretinoin and I understand that it is my responsibility not to get pregnant 1 month before, during isotretinoin or for 1 month after I stop taking isotretinoin.

INITIAL: _____

I NOW AUTHORIZE MY DOCTOR _____ TO BEG N MY TREATMENT WITH ISOTRETINO N.

PATIENT SIGNATURE: _____ DATE: _____

PARENT/GUARDIAN SIGNATURE (IF UNDER AGE 18): _____ DATE: _____

PLEASE PR NT: PAT ENT NAME AND ADDRESS _____ TELEPHONE _____

I HAVE FULLY EXPLAINED TO THE PATIENT, _____, THE NATURE AND PURPOSE OF THE TREATMENT DESCRIBED ABOVE AND THE RISKS TO FEMALE PAT ENTS OF REPRODUCTIVE POTENTIAL. I HAVE ASKED THE PATIENT IF SHE HAS ANY QUESTIONS REGARDING HER TREATMENT WITH ISOTRETINOIN AND HAVE ANSWERED THOSE QUESTIONS TO THE BEST OF MY ABILITY.

DOCTOR SIGNATURE: _____ DATE: _____

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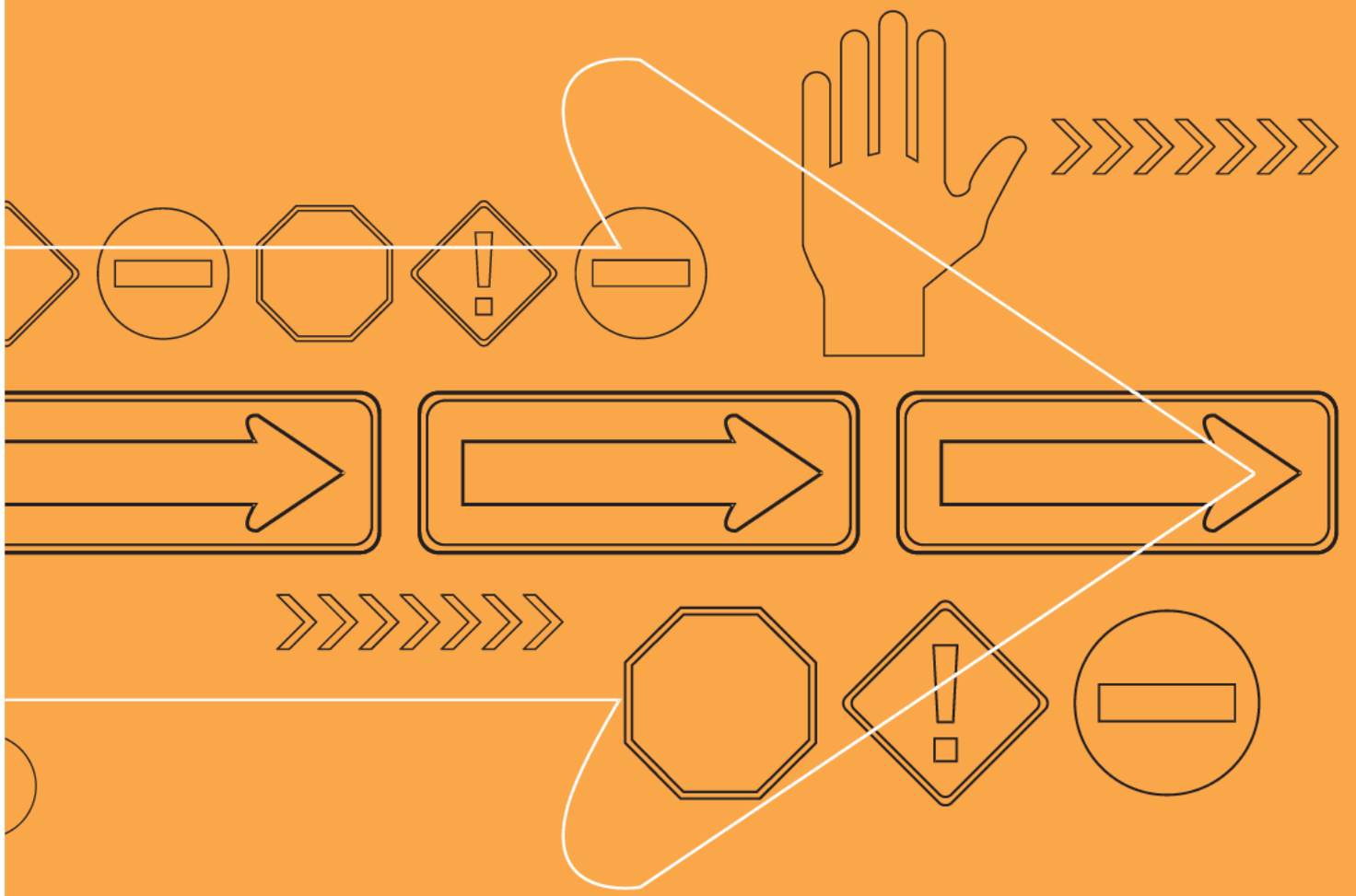
PRE_FORM02 SEP 15

**PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD.
PLEASE PROVIDE A COPY TO THE PATIENT.**

Reference ID: 3956479

Patient Flowchart



A flowchart to assist you with the iPLEDGE Program requirements

REGISTERED PATIENTS

iPLEDGE™
Committed to Pregnancy Prevention

Females of reproductive potential (FRP)

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Sign** a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- **Get** a screening urine/blood pregnancy test
- **Receive** patient ID card
- **Choose** 2 effective forms of birth control
- **Start** using the 2 forms of birth control simultaneously for at least 1 month
- **Get** a second pregnancy test within the first 5 days of your menstrual period (patient with irregular cycle please check with your prescriber) in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and to enter the 2 chosen forms of birth control. You can only answer your questions after your doctor has entered your test results into the iPLEDGE Program System
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **Use** the 2 forms of birth control Simultaneously
- **See** your doctor for a monthly pregnancy test in an approved lab
- **Access*** the iPLEDGE Program system to answer questions and confirm the 2 forms of birth control
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Get** a pregnancy test in an approved lab the last dose
- **Continue** to use the 2 forms of birth control simultaneously for 1 month after the last dose
- **Do not** donate blood for 1 month after the last dose
- **Get** a final pregnancy test 1 month after the last dose

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

BEFORE TREATMENT

- **Sign** a Patient Information/Informed Consent (for all patients) form for treatment
- **Receive** patient ID card
- **Get** a prescription for a maximum 30-day supply

EACH MONTH DURING THERAPY

- **See** your doctor to get a prescription
- **Get** a prescription for a maximum 30-day supply
- **Do not** donate blood

AFTER TREATMENT

- **Do not** donate blood for 1 month after after your last dose

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

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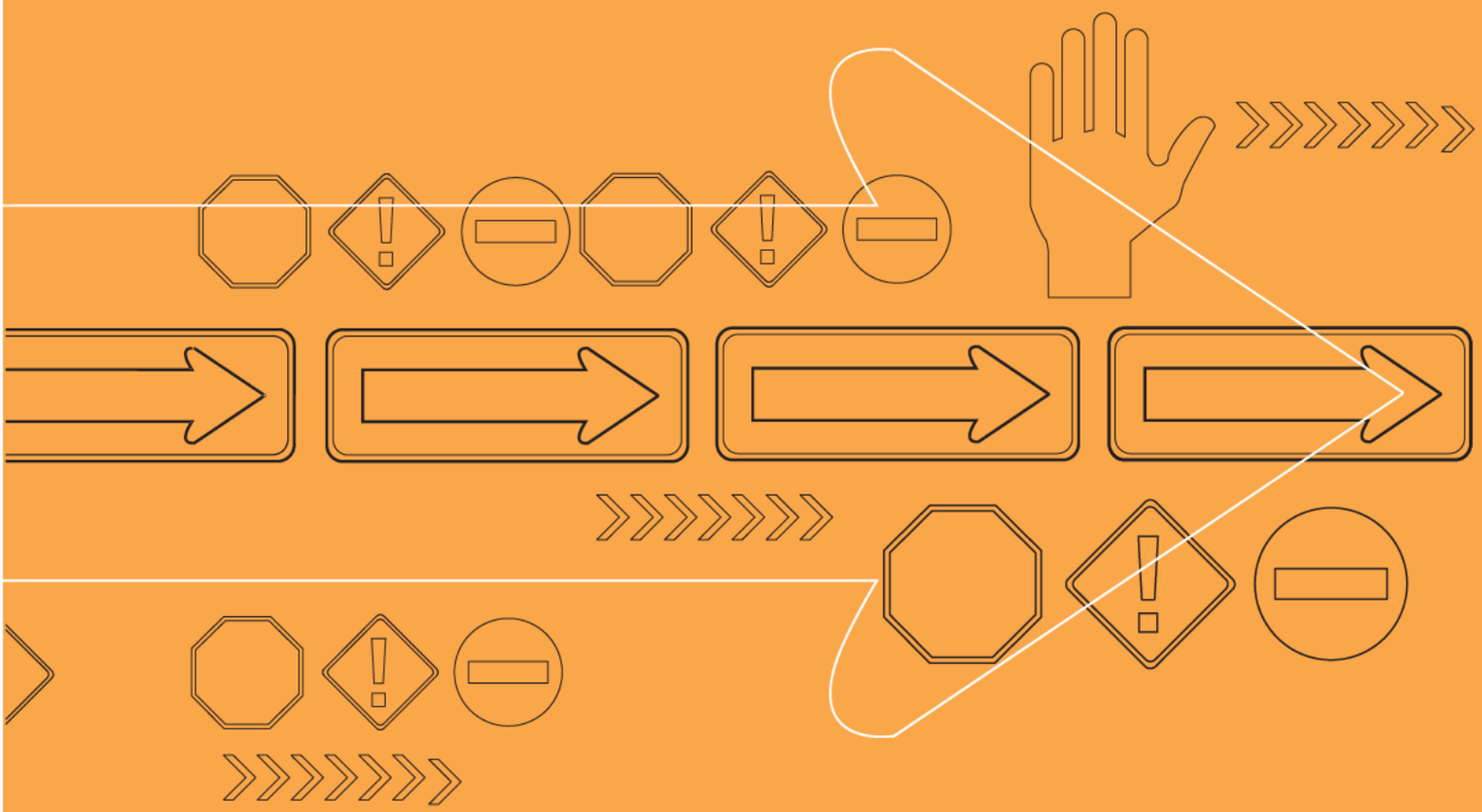

www.ipledgeprogram.com 1-866-495-0654

WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE

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

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

iPLEDGE™

Committed to Pregnancy Prevention

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Reference ID: 3956479