



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

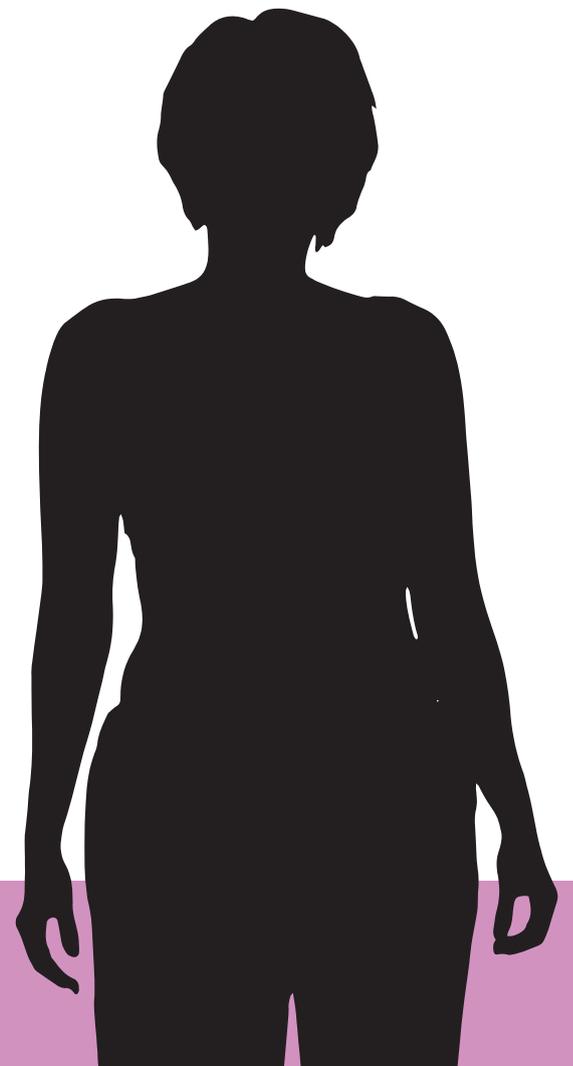
For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment.

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.



- **Safety Information About Isotretinoin**
- **iPLEDGE® Program Birth Control Information Sheet/
iPLEDGE Program Checklist**
- **Birth Control Workbook**



- **Guide to Isotretinoin For Female Patients Who Can Get Pregnant**
 - **Patient Identification Cards**
 - **Patient Information/Informed Consent About Birth Defects**
- **Contraception Counseling Guide And Contraception Referral Form**





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 methods 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 methods of birth control.** To access the iPLEDGE Program system, go to www.ipleadgeprogram.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 methods 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 healthcare professionals. You can also call iPLEDGE® Program at 1-866-495-0654 or visit www.ipledgeprogram.com.



iPLEDGE®
Committed to Pregnancy Prevention



Choose 1 Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*	How to Use it	MORE EFFECTIVE	How Well it Works	Benefits†	Risks†
Hormonal Implant 	Placed under skin of arm by a clinician. Works for 3 years. ¹		>99% ¹	<ul style="list-style-type: none"> Nothing to do or remember Light or no periods May decrease acne No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods
Hormonal IUD 	Placed in uterus by clinician. Self-check monthly. Works for 5 years. ¹		>99% ¹	<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods
Non-Hormonal IUD 	Placed in uterus by a clinician. Self-check monthly. Works for 10 years. ³		>99% ¹	<ul style="list-style-type: none"> No hormones Periods remain regular Effective immediately No increased risk of clots 	<ul style="list-style-type: none"> May cause heavier periods and cramping
Tubal Sterilization 	Surgical procedure to close the tubes between the uterus and the ovaries.		>99% ²	<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have child later, it is very difficult to re-open the tubes
Male Vasectomy 	Surgical procedure that closes off the tubes that carry a partner's sperm.		>99% ²	<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have child later, it is very difficult to re-open the tubes
Hormonal Shot 	Given every 3 months by a clinician.		>97% ¹	<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods May cause weight gain
Vaginal Ring 	You place in vagina. Replace monthly.		92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots
Hormonal Patch 	You place on skin. Replace weekly.		92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots
Birth Control Pill (Combination Type) 	Swallow at the same time daily.	92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots 	

Secondary Method of Birth Control (Choose One)	How to Use it	Benefits	Risks
Condoms (with or without spermicide)	Partner must be willing to use each and every time you have sex.	<ul style="list-style-type: none"> Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS 	<ul style="list-style-type: none"> Allergic Reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in vagina before you have sex.	<ul style="list-style-type: none"> You are in control of its use 	<ul style="list-style-type: none"> Allergic Reactions

One of the most common reasons that women get pregnant is that they engage in sexual activity when they planned to be abstinent
 Abstinance means that you commit to not having sex or sexual contact with any male 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after your isotretinoin treatment.

*Consult your doctor if you are considering choosing 2 primary methods of birth control rather than a primary and secondary method.
 †Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.
 ‡All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.
 References 1. Werner CA, Papic MJ, Ferris LK, Schwartz EB. Promoting safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol.* 2015;151(4):389-393. 2. Trussell, J. Contraception failure in the United States. *Contraception.* 2011;83:397-404. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014. 3. ParaGard® Prescribing Information, Teva Women's Health, Inc., June 2013.



BEFORE TREATMENT

PLANNING

- Talk** with your doctor about isotretinoin and the iPLEDGE Program
- Sign** the Patient Information/Informed Consent (for all patients) form
- Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- Have** your first urine or blood pregnancy test, which can be performed at the doctor's office
- Registration**—ensure your doctor registers you in the iPLEDGE Program. You must be registered for at least 30 days prior to your first prescription.
- Get** your patient ID card containing your patient ID number from your doctor. Keep your patient ID number in a safe place.
- Receive** your password in the mail

BIRTH CONTROL

- Read** the enclosed Birth Control Information Sheet and for additional information on birth control options read the enclosed Birth Control Workbook
- Talk** with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options
- Choose 2** effective methods of birth control
- Start** using the 2 methods of birth control together for at least 1 month before you start isotretinoin

YOUR FIRST PRESCRIPTION

- Have** a second pregnancy test conducted at an approved lab within the first 5 days of your menstrual period (at least 30 days after registration)
- Answer** questions about the iPLEDGE Program and confirm your 2 methods of birth control
 - **Note: you can answer your comprehension questions only 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
 - **Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack and provide fewer than 10 capsules**
- Obtain** your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1
 - 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 methods of birth control together all the time
- Keep** your appointments every month to get a prescription
- See** your doctor for a monthly pregnancy test
- Answer** different questions each month about the iPLEDGE Program

DURING TREATMENT

- Use 2** effective methods 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 methods of birth control by entering them into the iPLEDGE Program System
- Answer** different questions each month about the iPLEDGE Program
 - **Note: you can answer your comprehension questions only 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
- Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1
 - 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

- Get** a pregnancy test after your last dose
- Confirm** that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System
- Continue** using your 2 methods of birth control for 1 month
- Do not share any leftover isotretinoin with anyone**
- Do not donate** blood for 1 month after your last dose

ONE MONTH AFTER YOUR LAST DOSE

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

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

Most Recent Modification:
MONTH YEAR



iPLEDGE[®]
Committed to Pregnancy Prevention

The iPLEDGE Program



Birth Control Workbook

The guide to help you decide which methods 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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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.

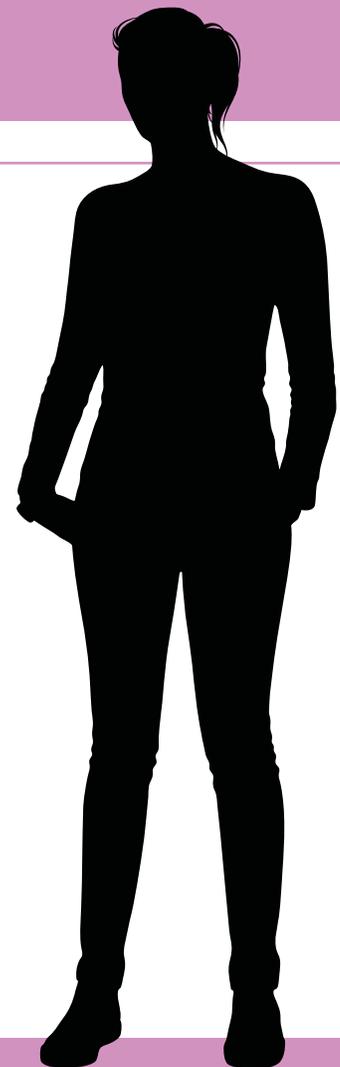




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Preventing Pregnancies

Not all methods 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/prescriber to help you decide what to do.

Read This Birth Control Workbook

To find out which birth control is effective for the iPLEDGE® Program, read this *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 which methods of birth control you would really use. Then talk with your doctor/prescriber or a birth control expert.

Share this workbook with your partner. Talk with your partner about how to use the birth control methods you choose and 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. You may need to take isotretinoin for 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 methods you choose.

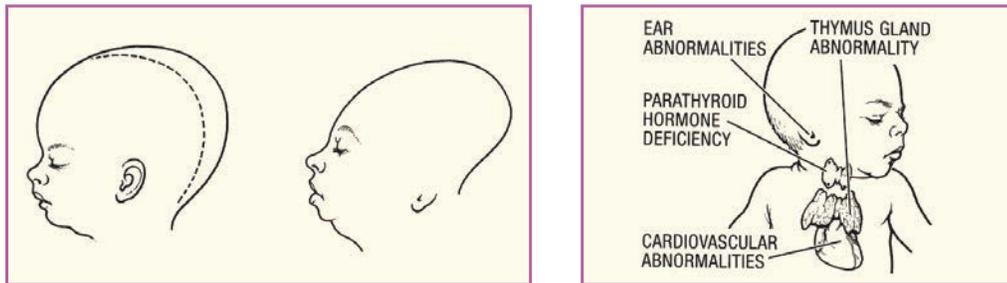


Please see accompanying complete product information, including CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.



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 methods of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- During treatment which usually lasts 4 to 5 months
- For 1 month after your last dose—to continue 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/prescriber has confirmed this
- You do not have either of your 2 ovaries and/or a uterus, and your doctor/prescriber has confirmed this

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

How Should I Use This Workbook?

Use this workbook as a guide to help you decide which 2 effective birth control methods are best for you during your treatment. You will want to pick a birth control method that works for you and gives you the best protection against pregnancy (primary method). Since all methods of birth control can fail, you must also pick a second method (another primary method or a secondary method) 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/prescriber 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 *Contraception Counseling Guide And Contraception Referral Form*. The referral form is in the pocket of the *Contraception Counseling Guide And Contraception Referral Form* booklet. The *Contraception Counseling Guide* outlines the birth control requirements and the effective methods of birth control of the iPLEDGE Program for the birth control expert. The referral form should be filled out by your doctor/prescriber and taken with you to the birth control counselor.



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

Why Do I Have To Use 2 Methods of Birth Control Together?

- Any single birth control method can fail
- Using 2 methods 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 method of birth control!

Can I Use Any 2 Methods of Birth Control?

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

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

- **Primary methods** do not fail very often. Be sure to choose a primary method that gives you the lowest chance of failure. This depends on such things as how well you remember to take medicine every day, whether your partner has had a vasectomy, or you have any medical conditions.
- **Secondary methods** include barrier methods and other methods of birth control. The most important thing about a secondary method is using it every time you have sex.
 - **Barrier methods** keep sperm from entering the uterus. Barrier methods 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 method, and it can be used with or without spermicide.
 - **Other methods** (vaginal sponge) contain spermicide.

Preventing Pregnancy by Abstinence (Not Having Sex)

Abstinence means that you commit to not having sex or sexual contact with any male 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after your isotretinoin treatment. This can be hard to do, especially if you have previously been sexually active.

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 contact your prescriber before engaging in sexual activity. You must not take isotretinoin if you cannot 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 usually fail because you may forget to take them as directed by your healthcare 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 methods, 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 method of birth control as you read this workbook.



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



Choose 1 Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*	How to Use it	MORE EFFECTIVE	How Well it Works	Benefits†	Risks‡
 Hormonal Implant Placed under skin of arm by a clinician. Works for 3 years. ¹	>99% ¹		<ul style="list-style-type: none"> Nothing to do or remember Light or no periods May decrease acne No increased risk of clots 	Irregular Periods	
 Hormonal IUD Placed in uterus by clinician. Self-check monthly. Works for 5 years. ¹	>99% ¹		<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	Irregular Periods	
 Non-Hormonal IUD Placed in uterus by a clinician. Self-check monthly. Works for 10 years. ³	>99% ¹		<ul style="list-style-type: none"> No hormones Periods remain regular Effective immediately No increased risk of clots 	May cause heavier periods and cramping	
 Tubal Sterilization Surgical procedure to close the tubes between the uterus and the ovaries.	>99% ²		<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	If you want to have child later, it is very difficult to re-open the tubes	
 Male Vasectomy Surgical procedure that closes off the tubes that carry a partner's sperm.	>99% ²		<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	If you want to have child later, it is very difficult to re-open the tubes	
 Hormonal Shot Given every 3 months by a clinician.	>97% ¹		<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	Irregular Periods May cause weight gain	
 Vaginal Ring You place in vagina. Replace monthly.	92% ¹		<ul style="list-style-type: none"> Lighter periods May decrease acne 	Blood clots	
 Hormonal Patch You place on skin. Replace weekly.	92% ¹		<ul style="list-style-type: none"> Lighter periods May decrease acne 	Blood clots	
 Birth Control Pill (Combination Type) Swallow at the same time daily.	92% ¹		<ul style="list-style-type: none"> Lighter periods May decrease acne 	Blood clots	

Secondary Method of Birth Control (Choose One)	How to Use it	Benefits	Risks
Condoms (with or without spermicide)	Partner must be willing to use each and every time you have sex.	<ul style="list-style-type: none"> Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS 	Allergic Reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in vagina before you have sex.	<ul style="list-style-type: none"> You are in control of its use 	Allergic Reactions

*Consult your doctor if you are considering choosing 2 primary methods of birth control rather than a primary and secondary method.

†Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.

‡All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.

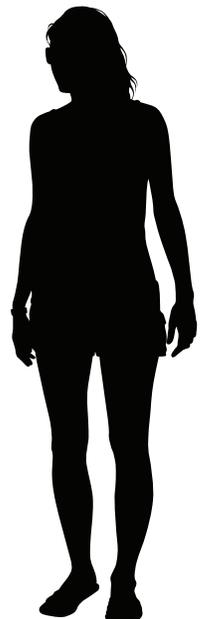
References 1. Werner CA, Papic MJ, Ferris LK, Schwartz EB. Promoting safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol.* 2015;151(4):389-393. 2. Trussell J. Contraception failure in the United States. *Contraception.* 2011;83:397-404. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014. 3. ParaGard® Prescribing Information, Teva Women's Health, Inc., June 2013.

Birth Control Methods That Are NOT Acceptable in The iPLEDGE® Program

You cannot use the following methods of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second method 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 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.*
- Breastfeeding
- 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.*

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*A cervical shield should not be confused with a cervical cap, which is an effective secondary method of contraception.

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

Making a Choice About Birth Control

General Advice

Your dermatologist, gynecologist, or family doctor will help you choose the right methods for you. They will also give you exact instructions on how to use them.

Choose methods that you will actually use all the time. This workbook will help you choose the 2 birth control methods that will be best for you.

Stay with your current primary method of birth control if:

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

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

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

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

What If I Cannot Use 2 Methods 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 methods 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.

Planning Ahead If You Have a Partner

- Make sure your partner knows the facts about isotretinoin and birth defects. Show him the information on birth defects in this workbook. Your partner should understand the risks and benefits of isotretinoin.
- Make sure he knows you have to use 2 methods of birth control together correctly all the time for at least 1 month before beginning isotretinoin treatment, during treatment, and 1 month after the last dose of isotretinoin.

Primary Methods of Birth Control

This section of the workbook provides information about the different methods 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 methods. If you want more information, ask your dermatologist, gynecologist, or family doctor.

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

Hormonal Birth Control Methods

Hormonal birth control methods include birth control pills (combination type), skin patches, shots, under-the-skin implants, and the vaginal ring. They are prescription medicines that prevent pregnancy.



Hormonal Shots—Single Hormone

Hormonal shots use a progestin (a birth control 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?

Some of the reasons you should not take single hormonal shots include:

- Unexplained vaginal bleeding
- History of or currently have breast cancer
- History of or currently have liver problems
- Pregnancy



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

How do I take single hormonal shots?

Your dermatologist, gynecologist, family doctor, or pharmacist (in some states) can give you a shot once every 12 weeks.

Are you taking single hormonal shots now?

If yes, is this going to be your primary method of birth control? How often do you miss shots?

Advantages

Some advantages may include:

- 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

Some disadvantages may include:

- Single hormonal shots do not protect against STIs (sexually transmitted infections) or HIV/AIDS
- 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 (IUD)

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

Who should not use a hormonal IUD?

Some of the reasons you should not use the hormonal IUD include:

- Conditions that may put you at risk for serious pelvic infection
- Unexplained vaginal bleeding
- Known or suspected cancer of the uterus, cervix, or breast
- Pregnancy

Hormonal Intrauterine Device (IUD) (Cont.)

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.

Do you have a hormonal IUD now?

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

- Is the IUD in place?
- When did you last have it checked by your clinician? It needs to be checked within 3 months after you had it inserted.

Advantages

Some advantages may include:

- It is a good choice for long-term birth control (5 years)
- There is no daily pill to take
- 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

Some disadvantages may include:

- An IUD does not protect against STIs (sexually transmitted infections) or HIV/AIDS
- Side effects may include cramps and heavy and/or longer menstrual periods for the first few months after it is placed, and increased chance of infection



Hormonal Implants (Under-The-Skin)

Implantable birth control is a small plastic rod(s) (the size of a matchstick) which releases birth control hormones, that is put under the skin in the upper arm in the doctor's/prescriber's office. It is effective for up to 3 years but can be removed earlier.

Who should not use

Some of the reasons you should not use implantable birth control include:

- Unexplained vaginal bleeding
- History of or currently have breast cancer
- History of or currently have liver disease
- Pregnancy



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

How do I use a hormonal implant?

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

Advantages

Some advantages may include:

- The plastic rod implant works for up to 3 years
- There is no daily pill to take

Disadvantages

Some disadvantages may include:

- Implant does not protect against STIs (sexually transmitted infections) or HIV/AIDS
- May cause cramping or irregular bleeding
- There can be side effects related to putting in the implant and removing it. Discuss this with your doctor/prescriber.
- May be less effective in women who are overweight. Discuss this with your doctor/prescriber.
- Isotretinoin, antibiotics, and St. John's Wort may make the implant less effective

How soon does the implant work?

Discuss this with your doctor/prescriber. **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 doctor/prescriber.**



Hormonal Birth Control Pills (Combination Type)

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

Who should not take birth control pills?

Some of the reasons you should not use birth control pills include:

- Smoking and you are over the age of 35
- History of or currently have blood clots
- History of or currently have breast cancer
- History of or currently have heart disease, liver problems, high blood pressure, or diabetes
- Pregnant or nursing

Hormonal Birth Control Pills (Cont.)

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 method of birth control is taking them every day to keep the chance of pregnancy as low as possible. If you have not used them correctly, you may need to choose another primary method 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 method 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 method of birth control.



Progesterone-only birth control pills (mini-pills) are not acceptable for the iPLEDGE® Program because they are not an effective method of birth control. If you are using these, you will have to choose another primary method 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 choose a method of birth control other than birth control pills during isotretinoin treatment.

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

Advantages

Some advantages may include:

- Many patients have more regular, lighter, shorter, and less painful periods

Disadvantages

Some disadvantages may include:

- 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 higher
- 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 1 pill, take it as soon as you remember. Continue taking your other pills at the regular time. Call your doctor/prescriber 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/prescriber 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.



Hormonal Skin Patch

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

Who should not use the hormonal skin patch?

Some of the reasons you should not use the patch include:

- Smoking and you are over the age of 35
- History of or currently have blood clots
- History of or currently have breast cancer
- History of or currently have heart disease, liver problems, high blood pressure, or diabetes
- Pregnancy or nursing

Hormonal Skin Patch (Cont.)

How do I use the hormonal skin patch?

You put on 1 patch which is worn for 1 week and replaced on the same day 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.

Are you using the hormonal skin patch now?

If you are, is this going to be your primary method 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 method of birth control may be better for you.

Advantages

Some advantages may include:

- There is no daily pill to take
- Many patients have more regular, lighter, and shorter periods

Disadvantages

Some disadvantages may include:

- 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 methods less effective
- Possible increased risk of blood clots. Please discuss this with your doctor/prescriber.



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



Hormonal Vaginal Ring

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

Who should not use the hormonal vaginal ring?

Some of the reasons you should not use the hormonal vaginal ring include:

- Smoking and you are over the age of 35
- History of or currently have blood clots
- History of or currently have breast cancer
- History of or currently have heart disease, liver problems, high blood pressure, or diabetes
- Pregnancy 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 1-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 method 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 method of birth control may be better for you.

Hormonal Vaginal Ring (Cont.)

Advantages

Some advantages may include:

- There is no daily pill to take
- It does not need to be fitted by a doctor/prescriber
- Many female patients have more regular, lighter, and shorter menstrual periods

Disadvantages

Some disadvantages may include:

- 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 methods less effective



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



Non-hormonal Intrauterine Device (Copper IUD)

The copper 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 IUD?

Some of the reasons you should not use the copper IUD include:

- Conditions that may put you at risk for serious pelvic infection
- Unexplained vaginal bleeding
- Known or suspected cancer of the uterus, cervix, or breast
- Wilson's disease (a rare inherited disorder that causes too much copper to accumulate in your liver, brain, and other vital organs)
- Pregnancy

How do I use the copper IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The copper IUD can stay in place for up to 10 years.

Advantages

Some advantages may include:

- You can use it if you cannot take hormones
- It is a good choice for long-term birth control
- There is no daily pill to take

Disadvantages

Some disadvantages may include:

- An IUD does not protect against STIs (sexually transmitted infections) or HIV/AIDS
- Side effects may include cramps, irregular bleeding, or heavy and longer menstrual periods

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Tubal Sterilization (Blocking Your Tubes)

Tubal sterilization (blocking your tubes) may be accomplished using a variety of surgical techniques that close the tubes between the uterus and the ovaries so that the sperm cannot get through to the egg. Tubal sterilization is considered to be very effective, virtually a permanent method of pregnancy prevention.

While an effective method of birth control, hysteroscopic tubal sterilization is not effective immediately and requires that a test be done at 3 months after the procedure 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.

Advantages

Some advantages may include:

- It is a very effective and virtually permanent method of birth control
- There is no daily pill to take
- It works immediately after the surgery with the exception of hysteroscopic tubal sterilization

Disadvantages

Some disadvantages may include:

- 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 increases the chance of ectopic pregnancy (pregnancy in the tubes) if sperm manage to get through the blocked tubes



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



Male Vasectomy

A vasectomy is a surgical procedure that closes off the tubes that carry a partner's sperm. 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 method of birth control while taking isotretinoin. You must still use a second method of birth control.

Advantages

Some advantages may include:

- It is a very effective and virtually permanent method of birth control

Disadvantages

Some disadvantages may include:

- 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



Secondary Methods of Birth Control

Secondary methods of birth control do not adequately protect against pregnancy if they are the only method used. However, they greatly increase your protection against getting pregnant if you use them along with a primary method every time you have sex. Effective secondary methods of birth control methods include barrier methods (male latex condoms, diaphragms, and cervical caps) and other methods (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 a spermicide. The vaginal sponge contains a spermicide. If a secondary method is your second method of birth control, you must use it every time you have sex. The female condom is not an effective secondary method for the iPLEDGE® Program.

Always use a spermicide with diaphragms and cervical caps.

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

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



Spermicides

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

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



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



Male Latex Condom With or Without a Spermicide

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

Choosing a male latex condom as your secondary method

If you choose male latex condoms as a secondary method, 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?
- 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.

Who should not use male latex condoms?

Some of the reasons your partner should not use male latex condoms (as your secondary method) include:

- You or your partner are allergic to latex
- 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 different method **you** can control and insert before having sex.

How does my partner use it?

The male latex condom is unrolled on a male’s erect penis before sex. Waiting too long lets sperm leak out.

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

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

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



*K-Y[®] Jelly is a registered trademark of Reckitt Benckiser LLC.

Male Latex Condom With or Without a Spermicide (Cont.)

Advantages

Some advantages may include:

- It is effective immediately when put on correctly Male latex condoms *do* offer some protection against STIs (sexually transmitted infections) and HIV/AIDS
- You can usually tell when it breaks or slips off

Disadvantages

Some disadvantages may include:

- Your partner has to be committed to using male latex condoms. Some males do not like or want to use them. You are not in control of this birth control method.
- Male latex condoms can break or slip off during sex
- Males and females can have an allergy to latex



Diaphragm (Must Be Used With a Spermicide)

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.

Choosing a diaphragm as your secondary method

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 1 of these 2 groups, talk with your dermatologist, gynecologist, family doctor, or birth control counselor about whether the diaphragm is right for you.

- Do you find it easy to put in your diaphragm and remember to use it each time you have sex?
- Have you been using a spermicide with the diaphragm? You must use a spermicide with your diaphragm when in the iPLEDGE® Program.
- Have you had your diaphragm checked by your doctor/prescriber 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.



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



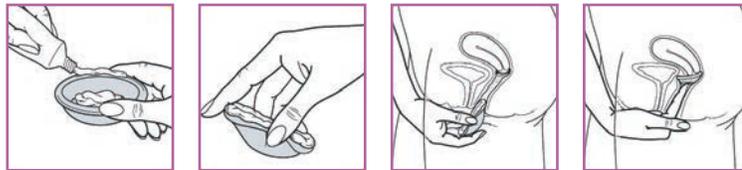
Who should not use the diaphragm?

Some of the reasons you should not use a diaphragm include:

- Allergy to latex or silicone
- Difficulty putting the diaphragm in and having it remain in place
- History of bladder infections or toxic shock
- Recent abortion

How do I use a diaphragm?

Before you insert the diaphragm, you put a spermicide in the center of the cup and around the ring. 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.



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 each time you have sex again and leave the diaphragm in place for 6 hours after the last time.** You should not leave the diaphragm in for more than 24 hours at a time.

Advantages

Some advantages may include:

- It is effective immediately when put in correctly and used with a spermicide
- You can easily carry a diaphragm with you and you are in control of its use
- You do not have to interrupt sex play—it can be inserted before sex

Disadvantages

Some disadvantages may include:

- A diaphragm does not protect against STIs (sexually transmitted infections) or HIV/AIDS
- You or your partner may have an allergy to latex
- Some females find it hard to insert
- It can get pushed out of place during sex
- You must check it for holes and tears and clean it after sex



Cervical Cap (Must Be Used With a Spermicide)

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

Choosing the cervical cap as your secondary method

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 1 of these 2 groups, talk with your gynecologist or family doctor about whether the cervical cap is right for you.

- Do you find it easy to put in your cervical cap and remember to use it each time you have sex?
- Have you been using spermicide with the cervical cap? You must use a spermicide with your cervical cap when in the iPLEDGE® Program

Who should not use a cervical cap?

Some of the reasons you should not use a cervical cap include:

- History of pelvic infections
- History of abnormal Pap tests
- History of Toxic Shock Syndrome (TSS)

How do I use a cervical cap?

The cap is filled one-third full with a 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 in place 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.



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 an extra spermicide if you have sex again. You can also leave the cap in place for a longer time—up to 48 hours. You cannot use the cervical cap if there is any vaginal bleeding, such as during your menstrual period.



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

Advantages

Some advantages may include:

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

Disadvantages

Some disadvantages may include:

- A cervical cap does not protect against STIs (sexually transmitted infections) or HIV/AIDS
- You cannot use it during your menstrual period
- A cap lasts about 1 year
- You must check it for holes and tears and clean it after sex



Vaginal Sponge

The vaginal sponge is a soft foam disc 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 before sex so it sits over your cervix. It has a string loop attached for easy removal.

Choosing the vaginal sponge as your secondary method

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

- Do you find it easy to put in your vaginal sponge and remember to use it each time you have sex?
- Do you find it easy to take out?

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.

Vaginal Sponge (Cont.)

How do I take the sponge out?

Wait at least 6 hours after the last time you had sex 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.

Advantages

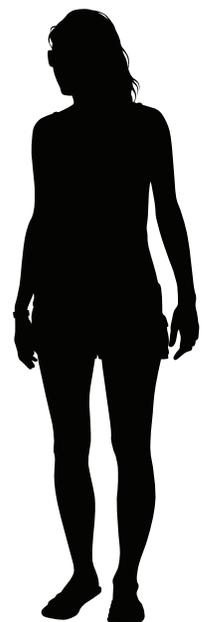
Some advantages may include:

- It is effective immediately
- You can easily carry a vaginal sponge with you and control its use
- 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

Disadvantages

Some disadvantages may include:

- 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 meant only for emergencies. It does NOT take the place of your usual 2 methods 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.

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 methods 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 ECPs, the more likely they are to work. It is best if ECPs are started within 12 hours after you have sex without adequate protection. The pills may give you severe nausea. Ask your doctor/prescriber for something to help with the nausea if you need this treatment. ECPs do not take the place of your usual birth control, nor do they continue to prevent pregnancy during the rest of your menstrual cycle.
2. **Copper IUD**—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/prescriber 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 method 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

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

Emergency Birth Control (Cont.)

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

Reasons Female Patients Get Pregnant

Some of the reasons female patients get pregnant:

- After they committed to be abstinent in the iPLEDGE® Program they did not avoid sex with a male
- They did not use **2** methods of birth control all the time and every time they had sex
- They did not use **2** methods of birth control the right way
- One method of birth control failed

It is very important that you use your **2** methods of birth control all the time and every time you have sex. If **2** methods of birth control are used every time properly, as the iPLEDGE Program requires, your chances of getting pregnant are very small.

Sex, Alcohol, and Drugs

Alcohol and drugs can make you unable to use good judgment. You must remember to use **2** effective methods of birth control together each and every time you have sex with a male for 1 month before you start taking isotretinoin, during, and for 1 month after stopping treatment. Remember to make good decisions to ensure you use your secondary method the right way.



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



Recognizing Pregnancy

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

- You miss your menstrual period
- You have nausea (generally 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

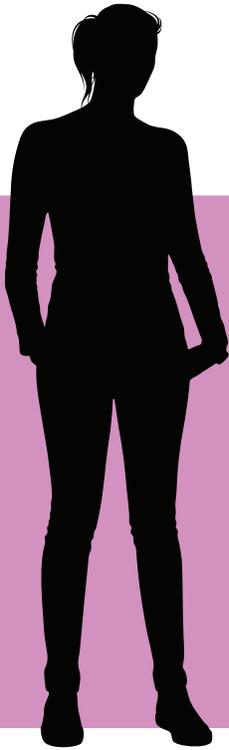
Sometimes a baby starts to grow outside the uterus. This is a serious problem. Call your doctor/prescriber right away, if you have these signs:

- 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



iPLEDGE[®]

Committed to Pregnancy Prevention



Web site: www.ipledgeprogram.com

Phone system: 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.

Most Recent Modification:
MONTH YEAR



iPLEDGE[®]
Committed to Pregnancy Prevention

The iPLEDGE Program



Guide to Isotretinoin 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

- Patient ID Cards and Informed Consent forms located inside back cover pocket

WARNING

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

Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

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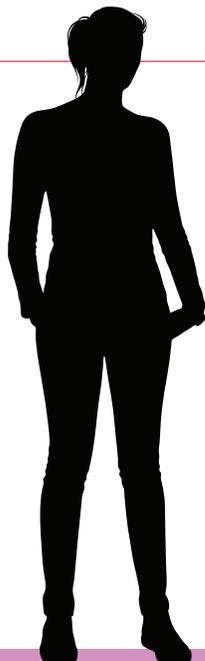




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*Located inside back cover pocket.



What Is Isotretinoin?

Isotretinoin (eye-soh-tret-in-OH-in) is a prescription medication that 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. You should also learn about the side effects and the precautions and warnings (see the enclosed sheet entitled *Safety Information About Isotretinoin*).

What Is The iPLEDGE® Program?

To avoid serious risks to unborn babies, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for isotretinoin. The iPLEDGE Program is a single, shared (includes multiple manufacturers) system with requirements for prescribers, pharmacies, and patients. The iPLEDGE Program also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE Program is to

- prevent pregnancies in females taking isotretinoin and to
- prevent pregnant females from taking isotretinoin

Only registered and activated prescribers can prescribe isotretinoin and only registered and activated pharmacies can dispense isotretinoin. In order to receive isotretinoin, all patients must be enrolled in the iPLEDGE Program and agree to follow the requirements.



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



What Do All Patients Need To Know?

Prevent Pregnancy and Birth Defects

There is a very high chance that babies born to female patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a female patient takes isotretinoin for only a short time. It may also happen if a pregnant female receives a blood transfusion from someone taking isotretinoin.

Do male patients taking isotretinoin need to worry about birth defects?

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin.

If you are worried about isotretinoin birth defects from sperm, you can use a male latex condom to help prevent pregnancy. Use a condom each and every time you have intercourse (sex) while you are taking isotretinoin and for 1 month after you stop taking it.

Can isotretinoin affect a male patient's ability to father healthy children?

Studies on isotretinoin did not show effects on sperm count, how sperm look, or how well they swim and move.

Do Not Donate Blood

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

Do Not Share Isotretinoin With Anyone

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

Obtain Your Prescription

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

The web site, www.ipledgeprogram.com, has a list of registered pharmacies. Once on the web site choose "Find a Participating Pharmacy" in the left navigation. 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.

What Do Female Patients Who Can Get Pregnant Need To Know?

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.

Before you can begin isotretinoin treatment, there is a 30-day wait period where you must be on 2 methods 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/prescriber 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 2 tests must be at least 19 days.

You must 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/prescriber when to take your pregnancy test each month.

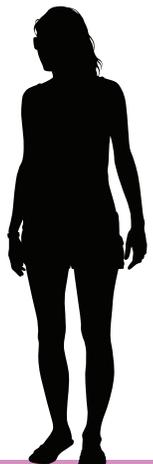
Have 2 negative pregnancy tests before you start isotretinoin.

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

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

- For at least 1 month before you start isotretinoin
- During treatment which usually lasts 4 to 5 months
- For 1 month after your last dose—to continue protection against pregnancy

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



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



Choose 1 Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*	How to Use it	MORE EFFECTIVE	How Well it Works	Benefits†	Risks‡
Hormonal Implant 	Placed under skin of arm by a clinician. Works for 3 years. ¹		>99% ¹	<ul style="list-style-type: none"> • Nothing to do or remember • Light or no periods • May decrease acne • No increased risk of clots 	• Irregular Periods
Hormonal IUD 	Placed in uterus by clinician. Self-check monthly. Works for 5 years. ¹		>99% ¹	<ul style="list-style-type: none"> • Light or no periods • No increased risk of clots 	• Irregular Periods
Non-Hormonal IUD 	Placed in uterus by a clinician. Self-check monthly. Works for 10 years. ³		>99% ¹	<ul style="list-style-type: none"> • No hormones • Periods remain regular • Effective immediately • No increased risk of clots 	• May cause heavier periods and cramping
Tubal Sterilization 	Surgical procedure to close the tubes between the uterus and the ovaries.		>99% ²	<ul style="list-style-type: none"> • It is a virtually permanent method of birth control • Nothing to do or remember 	• If you want to have child later, it is very difficult to re-open the tubes
Male Vasectomy 	Surgical procedure that closes off the tubes that carry a partner's sperm.		>99% ²	<ul style="list-style-type: none"> • It is a virtually permanent method of birth control • Nothing to do or remember 	• If you want to have child later, it is very difficult to re-open the tubes
Hormonal Shot 	Given every 3 months by a clinician.		>97% ¹	<ul style="list-style-type: none"> • Light or no periods • No increased risk of clots 	<ul style="list-style-type: none"> • Irregular Periods • May cause weight gain
Vaginal Ring 	You place in vagina. Replace monthly.		92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots
Hormonal Patch 	You place on skin. Replace weekly.		92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots
Birth Control Pill (Combination Type) 	Swallow at the same time daily.		92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots

Secondary Method of Birth Control (Choose One)	How to Use it	Benefits	Risks
Condoms (with or without spermicide)	Partner must be willing to use each and every time you have sex.	<ul style="list-style-type: none"> • Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS 	• Allergic Reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in vagina before you have sex.	<ul style="list-style-type: none"> • You are in control of its use 	• Allergic Reactions

*Consult your doctor if you are considering choosing 2 primary methods of birth control rather than a primary and secondary method.

†Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.

‡All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.

References 1. Werner CA, Papic MJ, Ferris LK, Schwartz EB. Promoting safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol.* 2015;151(4):389-393. 2. Trussell, J. Contraception failure in the United States. *Contraception.* 2011;83:397-404. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014. 3. ParaGard® Prescribing Information, Teva Women's Health, Inc., June 2013.

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

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

- You commit to abstinence which means not having sex or sexual contact with any male 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after your isotretinoin treatment.
- You are unable to get pregnant because:
 - You have entered menopause, and your doctor/prescriber has confirmed this
 - You do not have either of your 2 ovaries and/or a uterus, and your doctor/prescriber has confirmed this

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

You can only obtain your prescription for isotretinoin if:

- Your pregnancy test was negative
- Your doctor/prescriber entered your 2 methods of birth control in the iPLEDGE® Program system
- You answered your comprehension questions in the iPLEDGE Program system correctly. These questions will demonstrate your understanding of the iPLEDGE Program requirements, the birth control that you have chosen, and the risks associated with isotretinoin. **Note: you can answer your comprehension questions only after your doctor/prescriber has entered your pregnancy test result and confirmed your monthly office visit in the iPLEDGE Program system.** You will need your patient ID number to answer your comprehension questions on the iPLEDGE Program web site or by calling **1-866-495-0654**
- You also entered your 2 methods of birth control and they match the birth control options entered by your doctor/prescriber

Please read the iPLEDGE Program Birth Control Information Sheet and for additional information on birth control options read the enclosed *Birth Control Workbook*.



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

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

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/prescriber. 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/prescriber 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.

Obtaining Your Prescription

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.

The iPLEDGE Program system will automatically compute the “Do Not Dispense To Patient After” date for your pharmacist.

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

Day 1
Day of the pregnancy test
(Friday, March 1)

Day 2 – Day 6
(Saturday, March 2 thru
Wednesday, March 6)

**Day 7 – Last day to
obtain prescription**
(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 web site 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.

Talk With an Expert

If you want to talk to a birth control expert, such as a gynecologist or family doctor/prescriber, about your birth control, the doctor/prescriber who prescribes isotretinoin for you can refer you. The makers of isotretinoin will pay for this referred visit. Take the *Contraception Counseling Guide And Contraception Referral Form* with you.



Changing Your Birth Control

Tell the doctor/prescriber who prescribes your isotretinoin if you need to change your birth control during your isotretinoin treatment. Depending on the type of birth control you change to, you may have to **stop** isotretinoin and wait until you have been on the new birth control for at least 1 month and have a negative pregnancy test.

Changing From Abstinence

If you have chosen abstinence (not having sex or sexual contact with any male) and you decide to start having sexual activity, you must tell the doctor/prescriber who prescribes your isotretinoin before you engage in sexual activity. Before you continue isotretinoin, you and your doctor/prescriber must make a plan to start your birth control and be sure you are not pregnant.

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/prescriber 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.



Changing to a New Doctor/Prescriber

You can change your doctor/prescriber through the iPLEDGE Program web site, www.ipledgeprogram.com, by choosing “**Change Primary Prescriber**” from the menu or by calling **1-866-495-0654**. Once you make the change, you will not be able to get any more prescriptions from your original doctor/prescriber.

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.

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



iPLEDGE® Program Checklist

BEFORE TREATMENT

PLANNING

- Talk** with your doctor/prescriber about isotretinoin and the iPLEDGE Program
- Sign** the Patient Information/Informed Consent (for all patients) form
- Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- Have** your first urine or blood pregnancy test, which can be performed at the doctor's/prescriber's office
- Registration**—ensure your doctor/prescriber registers you in the iPLEDGE Program. You must be registered for at least 30 days prior to your first prescription.
- Get** your patient ID card containing your patient ID number from your doctor/prescriber. Keep your patient ID number in a safe place.
- Receive** your password in the mail

BIRTH CONTROL

- Read** the iPLEDGE Program Birth Control Information Sheet and for additional information on birth control options read the *Birth Control Workbook*
- Talk** with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options
- Choose 2** effective methods of birth control
- Start** using the 2 methods of birth control together for at least 1 month before you start isotretinoin

YOUR FIRST PRESCRIPTION

- Have** a second pregnancy test conducted at an approved lab within the first 5 days of your menstrual period (at least 30 days after registration)
- Answer** questions about the iPLEDGE Program and confirm your 2 methods of birth control
 - **Note: you can answer your comprehension questions only after your doctor/prescriber has entered your pregnancy test result in the iPLEDGE Program system**
- Obtain** your prescription for up to a maximum of a 30-day supply
 - **Note: isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack and provide fewer than 10 capsules.**
- Obtain** your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1
 - 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 methods of birth control together all the time
- Keep** your appointments every month to get a prescription
- See** your doctor/prescriber for a monthly pregnancy test
- Answer** different questions each month about the iPLEDGE Program

DURING TREATMENT

- Use 2** effective methods of birth control together all the time
- See** your doctor/prescriber for a monthly pregnancy test
- Keep** your appointments every month to get a prescription
- Confirm** your 2 methods of birth control by entering them into the iPLEDGE Program system
- Answer** different questions each month about the iPLEDGE Program
 - **Note: you can answer your comprehension questions only after your doctor/prescriber has entered your pregnancy test result in the iPLEDGE Program system**
- Obtain** your prescription for up to a maximum of a 30-day supply
- Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1
 - If you do not obtain your prescription within the 7-day prescription window, you will need to go back to your doctor/prescriber to start this process again
- Do not donate** blood

AFTER TREATMENT

RIGHT AFTER YOUR LAST DOSE

- Get** a pregnancy test after your last dose
- Confirm** that your doctor/prescriber has entered the results of this pregnancy test into the iPLEDGE Program system
- Continue** using your 2 methods of birth control for 1 month
- Do not share any leftover isotretinoin with anyone**
- Do not donate** blood for 1 month after your last dose

ONE MONTH AFTER YOUR LAST DOSE

- Have** a final pregnancy test at 1 month after your last dose
- Confirm** that your doctor/prescriber has entered the results of this pregnancy test into the iPLEDGE Program system

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

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



Patient Information/Informed Consent Informed Consent About Birth Defects

Important forms you must sign before you begin taking isotretinoin.

Patient Identification Cards

Remove one ID card and take it along with your prescription to the pharmacy (within your prescription window) to obtain your isotretinoin. Separate the cards and keep the duplicate ID card in a safe place.



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



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 *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, such as the *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.**



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

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

Read each item below and initial in the space provided to show that you understand each item and agree to follow your doctor's instructions. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

*A parent or guardian of a minor patient (under age 18) must also read and initial each item before signing the consent.

(Patient's Name)

- I understand that there is a very high chance that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking isotretinoin. This can happen with any amount and even if taken for short periods of time. This is why I must not be pregnant while taking isotretinoin.
Initial: _____
- I understand that I must not get pregnant one month before, during the entire time of my treatment, and for one month after the end of my treatment with isotretinoin
Initial: _____
- I understand that I must avoid sexual intercourse completely, or I must use two separate, effective methods of birth control (contraception) **at the same time**. The only exceptions are if I have had surgery to remove the uterus (a hysterectomy) or both of my ovaries (bilateral oophorectomy), or my doctor has medically confirmed that I am post-menopausal.
Initial: _____
- I understand that hormonal birth control products are among the most effective methods 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 method of birth control can fail. That is why I must use two different birth control methods at the same time, starting one month before, during, and for one month after stopping therapy every time I have sexual intercourse, even if one of the methods I choose is hormonal birth control.
Initial: _____
- I understand that the following are effective methods of birth control:

Primary methods <ul style="list-style-type: none"> • tying my tubes (tubal sterilization) • male vasectomy • intrauterine device • hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring) 	Secondary methods Barrier: <ul style="list-style-type: none"> • male latex condom with or without spermicide • diaphragm with spermicide • cervical cap with spermicide Other: <ul style="list-style-type: none"> • 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 one of my two methods of birth control must be a primary method.
Initial: _____
- I will talk with my doctor about any medicines including herbal products I plan to take during my isotretinoin treatment because hormonal birth control methods may not work if I am taking certain medicines or herbal products.
Initial: _____
- 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 Contraception Referral Form for this free consultation.
Initial: _____

- I must begin using the birth control methods I have chosen as described above at least one month before I start taking isotretinoin.
Initial: _____
- I cannot get my first prescription for isotretinoin unless my doctor has told me that I have two 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 one 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 two pregnancy tests, and the second test has been done in a lab.
Initial: _____
- I have read and understand the materials my doctor has provided to me, including the *Guide to Isotretinoin for Female Patients Who Can Get Pregnant*, *Birth Control Workbook* and *Patient Introductory Brochure*.
I have received information on emergency birth control.
My doctor provided me and asked me to watch a video about birth control and a video about birth defects and isotretinoin.
Initial: _____
- 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 two birth control methods at any time.
Initial: _____
- My doctor provided me information about the purpose and importance of providing information to the iPLEDGE Program should I become pregnant while taking isotretinoin or within one month of the last dose. I understand that if I become pregnant, information about my pregnancy, my health, and my baby's health may be shared with the makers of isotretinoin, authorized parties who maintain the iPLEDGE Program for the makers of isotretinoin, and government health regulatory authorities.
Initial: _____
- I understand that being qualified to receive isotretinoin in the iPLEDGE Program means that I:
 - have had two 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 two methods of effective birth control at the same time. At least one method must be a primary method of birth control, **unless I have chosen never to have sexual contact with a male (abstinence)**, or I have undergone a hysterectomy or bilateral oophorectomy, or I have been medically confirmed to be post-menopausal. I must use two methods of birth control for at least one month before I start isotretinoin therapy, during therapy, and for one 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 been informed of and understand the purpose and importance of providing information to the iPLEDGE Program should I become pregnant while taking isotretinoin or within 1 month of the last dose.
 - 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 methods 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 one month before, during isotretinoin treatment, or for one month after I stop taking isotretinoin.

Initial: _____

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

Patient Signature: _____ Date: _____

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

Please print: Patient Name and Address _____ Telephone _____

I have fully explained to the patient, _____, the nature and purpose of the treatment described above and the risks to females of reproductive potential. I have asked the patient if she has any questions regarding her treatment with isotretinoin and have answered those questions to the best of my ability.

Doctor Signature: _____ Date: _____

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

- Visit your doctor/prescriber 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 the prescription window to obtain your prescription
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information



iPLEDGE[®]
Committed to Pregnancy Prevention

Duplicate ID Card

- Visit your doctor/prescriber 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 the prescription window to obtain your prescription
- Do not get pregnant
- Do not share your drug
- Do not donate blood

See reverse for important safety information



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Peel off sticker for
patient's file



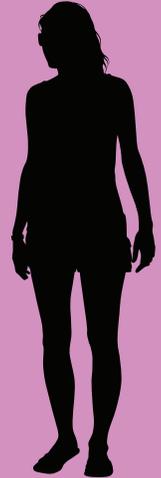
Patient ID number

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



iPLEDGE[®]

Committed to Pregnancy Prevention



Web site: www.ipledgeprogram.com

Phone system: 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.



Peel off sticker for patient's file



Patient ID number

<ul style="list-style-type: none"> • Visit your doctor monthly • Women who can get pregnant must: <ol style="list-style-type: none"> 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 the prescription window to obtain your prescription • Do not get pregnant • Do not share your drug • Do not donate blood  <p>See reverse for important safety information</p>	<p>Duplicate ID Card</p> <ul style="list-style-type: none"> • Visit your doctor monthly • Women who can get pregnant must: <ol style="list-style-type: none"> 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 the prescription window to obtain your prescription • Do not get pregnant • Do not share your drug • Do not donate blood  <p>See reverse for important safety information</p>
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<p>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:</p> <ul style="list-style-type: none"> • 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 <p>© 2016 JUN16</p>	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>© 2016 JUN16</p>
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Most Recent Modification:
MONTH YEAR



iPLEDGE[®]
Committed to Pregnancy Prevention

The iPLEDGE Program



Contraception Counseling Guide And Contraception Referral Form

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

WARNING

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

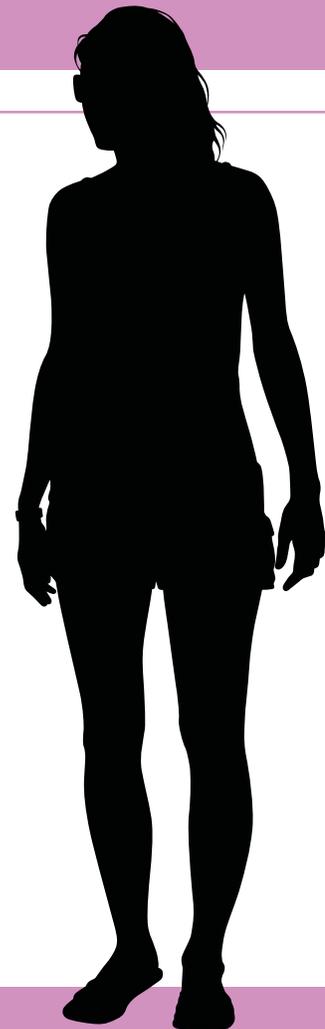


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*Located inside back cover pocket.



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



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}

What Is The iPLEDGE[®] Program?

To avoid serious risks to unborn babies, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for isotretinoin. The iPLEDGE Program is a single, shared (includes multiple manufacturers) system with requirements for prescribers, pharmacies, and patients. The iPLEDGE Program also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE Program is to

- prevent pregnancies in females taking isotretinoin and to
- prevent pregnant females from taking isotretinoin

Only registered and activated prescribers can prescribe isotretinoin and only registered and activated pharmacies can dispense isotretinoin. In order to receive isotretinoin, all patients must be enrolled in the iPLEDGE Program and agree to follow the requirements.



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

Your Role

This patient is being referred to you because she has asked for counseling to help her decide which contraceptive methods are best for her and that will enable her to comply with the contraception requirements of the iPLEDGE® Program.

The patient must select and commit to using **2** methods of effective contraception simultaneously, at least 1 of which must be a primary method, 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** methods of effective contraception for at least 1 month prior to initiation of isotretinoin treatment, during isotretinoin treatment, and for 1 month after discontinuing isotretinoin treatment.

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 *Contraception Counseling Guide And Contraception Referral Form* completely before you begin your counseling session. These provide an overview of the counseling goals for the patient and the contraception requirements of the iPLEDGE Program. They do not contain detailed information on the various methods of contraception.

The *Birth Control Workbook*, which is for patients, contains more information on effective primary and secondary methods of contraception. It is not complete information on any of the methods, and the patient is encouraged to ask questions about specific methods or issues. Additionally, the patient received an iPLEDGE Program Birth Control Information Sheet which lists the approved primary and secondary methods of birth control required for the iPLEDGE Program (www.ipledgeprogram.com).



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

iPLEDGE Program Approved Methods of Contraception



iPLEDGE[®]
Committed to Pregnancy Prevention

Choose 1 Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*	How to Use it	MORE EFFECTIVE	How Well it Works	Benefits†	Risks†
Hormonal Implant 	Placed under skin of arm by a clinician. Works for 3 years. ¹		>99% ¹	<ul style="list-style-type: none"> Nothing to do or remember Light or no periods May decrease acne No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods
Hormonal IUD 	Placed in uterus by clinician. Self-check monthly. Works for 5 years. ¹		>99% ¹	<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods
Non-Hormonal IUD 	Placed in uterus by a clinician. Self-check monthly. Works for 10 years. ³		>99% ¹	<ul style="list-style-type: none"> No hormones Periods remain regular Effective immediately No increased risk of clots 	<ul style="list-style-type: none"> May cause heavier periods and cramping
Tubal Sterilization 	Surgical procedure to close the tubes between the uterus and the ovaries.		>99% ²	<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have child later, it is very difficult to re-open the tubes
Male Vasectomy 	Surgical procedure that closes off the tubes that carry a partner's sperm.		>99% ²	<ul style="list-style-type: none"> It is a virtually permanent method of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have child later, it is very difficult to re-open the tubes
Hormonal Shot 	Given every 3 months by a clinician.		>97% ¹	<ul style="list-style-type: none"> Light or no periods No increased risk of clots 	<ul style="list-style-type: none"> Irregular Periods May cause weight gain
Vaginal Ring 	You place in vagina. Replace monthly.		92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots
Hormonal Patch 	You place on skin. Replace weekly.		92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots
Birth Control Pill (Combination Type) 	Swallow at the same time daily.	92% ¹	<ul style="list-style-type: none"> Lighter periods May decrease acne 	<ul style="list-style-type: none"> Blood clots 	

Secondary Method of Birth Control (Choose One)	How to Use it	Benefits	Risks
Condoms (with or without spermicide)	Partner must be willing to use each and every time you have sex.	<ul style="list-style-type: none"> Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS 	<ul style="list-style-type: none"> Allergic Reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in vagina before you have sex.	<ul style="list-style-type: none"> You are in control of its use 	<ul style="list-style-type: none"> Allergic Reactions

*Consult your doctor if you are considering choosing 2 primary methods of birth control rather than a primary and secondary method.

†Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.

‡All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.

References 1. Werner CA, Papp MJ, Ferris LK, Schwartz EB. Promoting safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol.* 2015;151(4):389-393. 2. Trussell, J. Contraception failure in the United States. *Contraception.* 2011;83:397-404. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014. 3. ParaGard® Prescribing Information, Teva Women's Health, Inc., June 2013.

Counseling Goals

Ensure That The Patient:

- Understands and commits fully to not becoming pregnant
- Commits to using 2 methods of contraception together simultaneously, consistently, and correctly. She must use 2 methods of effective contraception for at least 1 month prior to initiation of isotretinoin treatment, during isotretinoin treatment, and for 1 month after discontinuing isotretinoin treatment
- Chooses the methods of contraception that will work best for her and that she and her partner will actually use
- If, after counseling, the patient recognizes she will not be able to commit fully to the iPLEDGE® Program contraception requirements, encourage her to not take isotretinoin and do not prescribe or if counseling, inform her prescriber
- Commits fully to abstinence (not having sex or sexual contact with any male 24 hours a day, 7 days a week) for 1 month before, during, and for 1 month after she stops taking isotretinoin
- Knows when to contact her prescriber for emergency contraception
- Understands the risk of having a child with significant birth defects from exposure to isotretinoin

Counseling Younger Teens

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

- Why it is important to use 2 methods of birth control, 1 primary and 1 secondary at all times. 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 have unprotected sex or if their contraception method fails.



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

Contraception Requirements

Using 2 Methods of Contraception Provides More Protection

Use of 2 iPLEDGE Program approved methods of contraception (at least 1 of which is a primary method) simultaneously substantially reduces the risk that a female will become pregnant.

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 methods are less than 100% effective, the iPLEDGE Program requires the additional protection of a second method of contraception.

Selecting an Effective Primary Method of Contraception

Table 1 lists, by typical use failure rate, the primary methods of contraception acceptable in the iPLEDGE Program. The single most important decision in contraception for the iPLEDGE Program is selecting a primary method that the patient can and will use as correctly as possible. Other important factors to consider in counseling the patient on selecting a primary method include side effects, contraindications, and the patient's ability to use it correctly. All of these factors influence compliance with the iPLEDGE Program requirements to prevent pregnancy.

Hormonal Combination Oral Contraceptives as a Primary Method

If the patient is currently taking or planning to take oral contraceptives, review that section in the *Birth Control Workbook* with her. For a patient who has indicated she has difficulty taking oral contraceptives correctly, other contraception not requiring daily dosing may be a better choice. It is critical that such a patient choose a method other than daily oral contraceptive agents.



Table 1: Primary Methods of Contraception by Typical Use Failure Rate		
Method	Percentage of Females Experiencing an Unintended Pregnancy Within the First Year of Use ^a	
	Perfect Use	Typical Use
Implantable Hormones	0.05%	0.05%
Male Vasectomy	0.10%	0.15%
Hormonal IUD (LNg 20)	0.20%	0.20%
Tubal Sterilization	0.50%	0.50%
Non-hormonal IUD (Copper T380A) ^b	0.60%	0.80%
Hormonal Injectable (single)	0.20%	6.00%
Hormonal Transdermal Patch	0.30%	9.00%
Hormonal Vaginal Ring	0.30%	9.00%
Hormonal Combination Oral Contraceptives ^b	0.30%	9.00%

- a. Adapted from Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83:397–404. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014.
- b. The IUD Progesterone T and progestin-only “mini-pills” are not acceptable for the iPLEDGE® Program. (See “Unacceptable Methods Of Contraception” on page 9).

Selecting an Effective Secondary Method of Contraception

Table 2 lists the acceptable secondary methods of contraception in the iPLEDGE® Program. There are 2 methods of secondary contraception: barrier and other. Barrier methods include the diaphragm and cervical cap (both of which must be used with a spermicide) and the male latex condom (which can be used with or without a spermicide). The other method is the vaginal sponge, which contains a spermicide. The most important issue for a secondary method is that it be used correctly each time the patient has intercourse and that it be in place should the primary method fail.

Help the patient select a secondary method that she and her partner can fully commit to using correctly each time they have intercourse.

Table 2: Secondary Methods of Contraception Listed by Typical Use Failure		
Method	Percentage of Females Experiencing an Unintended Pregnancy Within the First Year of Use ^a	
	Perfect Use	Typical Use
Barrier Methods		
Male Latex Condom ^b	2%	18%
Diaphragm [*]	6%	12%
Cervical Cap ^{*,a}	9%	20%
Other Methods		
Vaginal Sponge ^c	9%	12%

- a. Adapted from Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83:397–404. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014.
- b. Male Latex Condom failure rates are for use without spermicide. Female condoms are not acceptable for the iPLEDGE Program (See “Unacceptable Methods Of Contraception” on page 9.)
- c. Failure rate for nulliparous women. The rate is approximately double for parous women.
- *Failure rates for diaphragm and cervical cap are for methods including the use of spermicide.

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

Unacceptable Methods of Contraception

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

- Progesterone-only “mini-pills”
- Female condoms
- Natural family planning (rhythm method or fertility awareness)
- Breastfeeding
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix*

Patients currently using these unacceptable methods of contraception must switch to iPLEDGE Program approved methods of contraception.

Emergency Contraception

Review this section in the *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 methods she selected.

Abstinence

For this program, all females of reproductive potential must fully commit to pregnancy prevention.

Isotretinoin is not recommended for any female of reproductive potential who cannot or will not follow the contraceptive requirements of the iPLEDGE Program. 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, she must understand that she has committed to not engaging in sex or sexual contact with any male 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after she stops taking isotretinoin.

One of the most common reasons that women get pregnant is that they engage in sexual activity when they planned to be abstinent.

*A cervical shield should not be confused with a cervical cap, which is an effective secondary method of contraception.

About The 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.

Reimbursement Form

Also in the back pocket 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**.

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 remind any patient who is pregnant to contact the doctor/prescriber who prescribed her isotretinoin.

REFERENCES

1. Lammer EJ, Chen DT, Hoar RM, et al. Retinoic acid embryopathy. *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, 2015.

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



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 methods 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:

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

Primary Method _____

Secondary or Second Primary Method _____

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



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 iPLEDGE. A blank W-9 form and instructions for completion can be found at www.irs.gov

Signature _____ Date _____



iPLEDGE[®]
Committed to Pregnancy Prevention

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

ISOTRETINOIN CONTRACEPTION REFERRAL FORM

Prescriber: Complete for Patients Being Referred for Contraception Counseling



iPLEDGE[®]
Committed to Pregnancy Prevention

iPLEDGE—Committed to Pregnancy Prevention
PO BOX 29094
Phoenix, AZ 85038

FAXABLE REIMBURSEMENT FORM

The Following Restrictions Apply:

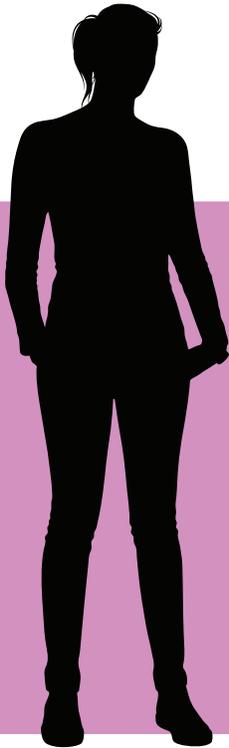
Only consulting clinicians who provide initial pregnancy prevention counseling are eligible for reimbursement for such counseling. Other services provided during this visit are not eligible for reimbursement. The physician prescribing isotretinoin, or any other person working under the direct supervision 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



iPLEDGE[®]

Committed to Pregnancy Prevention



Web site: www.ipledgeprogram.com

Phone system: 1-866-495-0654

WARNING

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



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

