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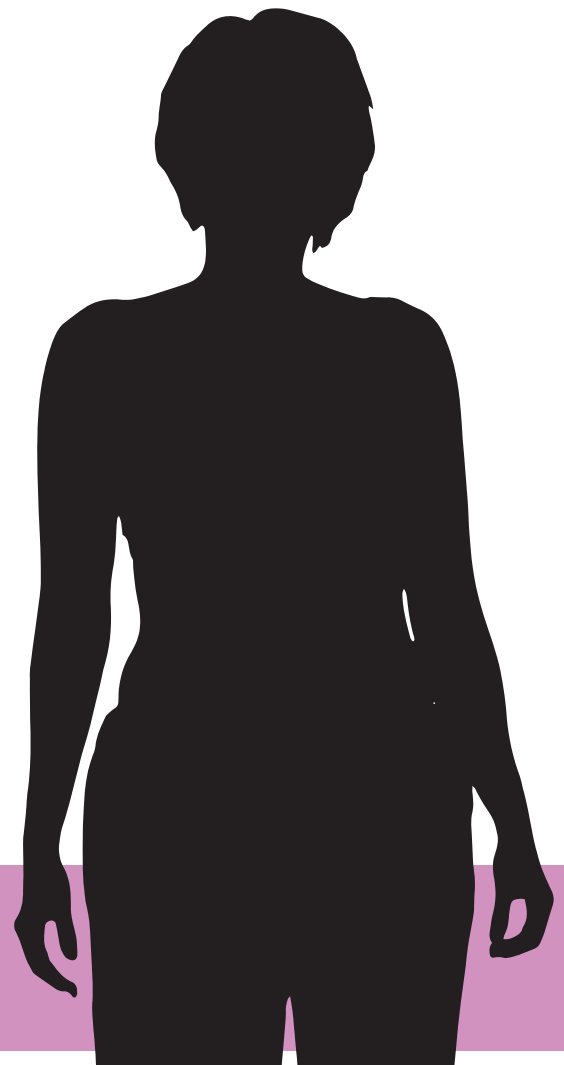
The iPLEDGE REMS



Guide For Patients Who Can Get Pregnant

The Importance of Avoiding Pregnancy on Isotretinoin

**The tools you need to help you prepare for
your isotretinoin treatment and prevent pregnancy**





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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), early (premature) births, and death of a baby. There is no accurate means of determining whether an exposed baby has been affected.

IMPORTANT NOTICE

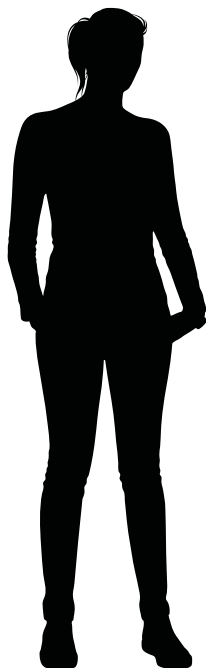
Use only isotretinoin products approved by the US Food and Drug Administration.

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



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What Is Isotretinoin?

Isotretinoin (eye-soh-tret-in-OH-in) is a prescription medication used in patients 12 years of age and older, who are not pregnant 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.

What Is The iPLEDGE® REMS?

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 REMS is a, shared (includes multiple manufacturers) system with requirements for prescribers, pharmacies, and patients. The iPLEDGE REMS also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE REMS is to

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

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



There is a very high chance that babies born to patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a patient takes isotretinoin for only a short time. It may also happen if a pregnant patient receives a blood transfusion from someone taking isotretinoin. It is important that you do not to use leftover medication and to dispose of the medication to avoid unintended exposed pregnancies.

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

Unlike in patients who **can** get pregnant, 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 any sexual contact (penis-vaginal) with a partner who could get you pregnant while you are taking isotretinoin and for 1 month after you stop taking it.

Does isotretinoin affect sperm count or sperm motility?

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 person 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 Donate Breastfeed

Do not breastfeed while taking isotretinoin and for one month after stopping isotretinoin. We do not know if isotretinoin can pass through your milk and harm the baby.

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 enrolled with and activated in the iPLEDGE REMS.

The website, www.ipledgeprogram.com, has a list of enrolled pharmacies. Once on the website, 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 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 forms of birth control. Additionally, you need to have 2 negative pregnancy tests. They can be urine or blood tests. You will need to plan with your doctor/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 (CLIA certified). 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.

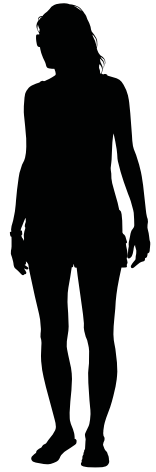
Have 2 negative pregnancy tests before you start isotretinoin.

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

To keep from getting pregnant, you need to use **2** effective forms 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 form of birth control can fail. Using **2** forms of birth control together all the time drastically reduces the chance that you will get pregnant.



MORE EFFECTIVE



MORE EFFECTIVE






6 iPLEDGE® REMS Approved Forms of Contraception









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Choose 1 Primary + 1 Secondary Birth Control Form

Primary Form of Birth Control (Choose One)*	How to Use it	How Well it Works	Benefits †	Risks †
 Hormonal Implant	Placed under the skin of the 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 the uterus by the clinician. Self-check monthly. Works for 3-5 years. ^{1,2,3}	>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 the uterus by the clinician. Self-check monthly. Works for 10 years. ⁴	>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 	A surgical procedure to close the tubes between the uterus and the ovaries.	>99% ⁵	<ul style="list-style-type: none"> It is a virtually permanent form of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have a child later, it is very difficult to re-open the tubes
Male Vasectomy 	A surgical procedure that closes off the tubes that carry a partner's sperm.	>99% ⁵	<ul style="list-style-type: none"> It is a virtually permanent form of birth control Nothing to do or remember 	<ul style="list-style-type: none"> If you want to have a 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 it in the vagina. Replace per prescriber's instructions.	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 it on the 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 Form of Birth Control (Choose One)	How to Use it	Benefits	Risks
Male Latex 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 and HIV/AIDS 	<ul style="list-style-type: none"> Allergic reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in the 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 patients get pregnant is that they engage in sexual activity when they planned to be abstinent
 Abstinence means that you commit to not having sexual contact (penis-vaginal) with a partner who could get you pregnant 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 forms of birth control rather than a primary and secondary form¹Benefits and Risks are not inclusive. Please review the Full Prescribing Information for the products listed.²All 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 the safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol* 2015;151(4):389-393. 2. Skyla® Prescribing Information, Bayer HealthCare Pharmaceuticals Inc., February 2018. 3. Liletta® Prescribing Information, Actavis Pharma, Inc., August 2017. 4. PARAGARD® Prescribing Information, Cooper Surgical Inc., January 2018. 5. Trussell, J. Contraception failure in the United States. *Contraception*. 2011;83:397-404. Available at ember 9, 2014.

Reasons You Would Not Have To Use 2 Forms Of Birth Control

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

- You commit to abstinence which means not having sexual contact (penis-vaginal) with a partner who could get you pregnant 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 a uterus and/or you do not have any ovaries, 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** forms of birth control in the iPLEDGE® REMS website
- You answered your comprehension questions in the iPLEDGE REMS website correctly. These questions will demonstrate your understanding of the iPLEDGE REMS 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 REMS website.** You will need your patient ID number to answer your comprehension questions on the iPLEDGE REMS website or by calling **1-866-495-0654**
- You also entered your **2** forms of birth control, and they match the birth control options entered by your doctor/prescriber



www.ipledgeprogram.com

1-866-495-0654

The iPLEDGE REMS 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 REMS Pregnancy Registry is a way to collect that information. It may help us prevent more pregnancies in the future.

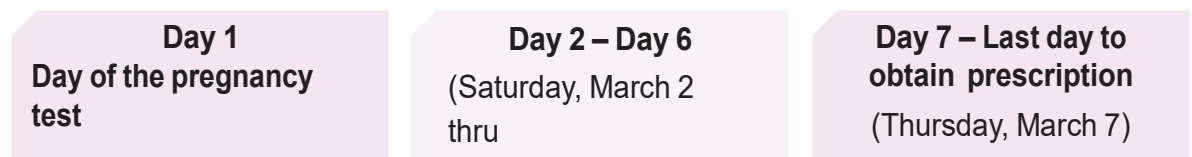
Your doctor/prescriber will tell you about the confidential iPLEDGE REMS Pregnancy Registry. You are encouraged to contact the iPLEDGE REMS Pregnancy Registry at **1-800-681-7247** if you get pregnant. If you become pregnant, you may receive follow up call(s) from your doctor / prescriber and/or a representative of the Pregnancy Registry.

Obtaining Your Prescription

The timeframe to obtain your prescription is 7 days (1 week), and Day 1 starts the day of the specimen collection for your pregnancy test. **After your doctor/prescriber has entered your pregnancy test result and confirmed your monthly office visit in the iPLEDGE REMS website, you can answer your comprehension questions.**

The iPLEDGE REMS website 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:



The 7-day timeframe to obtain your prescription expires at 11:59 p.m. Eastern Time on Day 7.

Your pharmacist will not be able to fill your prescription after this time.

If you do not obtain your prescription before the 7-day timeframe, and it is not your first prescription, you can get another pregnancy test and repeat the program requirements to get another prescription.

Additional information regarding the specific dates of your 7-day prescription timeframe and other information about your current status can be found by selecting “My Program Status” on the website from the Patient home page (after you log in).



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* 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 (penis-vaginal) with a partner who could get you pregnant) and you decide to start having sexual contact (penis-vaginal) with a partner who could get you pregnant, you must tell the doctor/prescriber who prescribes your isotretinoin before you engage in sexual contact (penis-vaginal) with a partner who could get you pregnant. 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. You will be required to wait 30 days while always using 2 forms of birth control before continuing treatment. You will need to have a negative pregnancy test, which starts the 30-day wait period. When the 30-day wait period is over, you will need to have a negative pregnancy test, complete your comprehension questions and be confirmed by your prescriber before continuing treatment.

One of the most common reasons that patients get pregnant is that they do not avoid sexual contact (penis-vaginal) with a partner who could get them pregnant when they plan to be abstinent.

Changing to a New Doctor/Prescriber

You can change your doctor/prescriber through the iPLEDGE REMS website, 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.

Patient Identification Number

Upon completing your enrollment into the iPLEDGE REMS, you will receive your iPLEDGE ID that includes a QR code by your preferred method of communication. You must fill your prescription within your prescription window to obtain your isotretinoin. The QR code can be used by your pharmacy to dispense your prescription. You can also use the QR code to obtain educational materials, access your iPLEDGE REMS profile, and complete your *iPLEDGE REMS Comprehension Questions*.

Isotretinoin Products

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

www.ipledgeprogram.com

1-866-495-0654



iPLEDGE® REMS Checklist

BEFORE TREATMENT

PLANNING

- Talk** with your doctor/prescriber about isotretinoin and the iPLEDGE REMS
- Have** your first urine or blood pregnancy test, which can be performed at the doctor's/prescriber's office
- Enrollment**—ensure your doctor/prescriber enrolls you in the iPLEDGE REMS. You must be enrolled for at least 30 days prior to your first prescription.
- Sign** the Patient Enrollment Form for Patients who can get Pregnant
- Get** your patient ID number and ensure access to educational materials. Keep your patient ID number in a safe place.
- Receive** your password by your preferred method of communication.

BIRTH CONTROL

- Read** the iPLEDGE REMS Guide for Patients who Can Get Pregnant for additional information on birth control options
- Talk** with your dermatologist, gynecologist, family doctor, or birth control expert about effective birth control options
- Choose 2** effective forms of birth control
- Start** using the 2 forms of birth control together for at least 1 month before you start isotretinoin

YOUR FIRST PRESCRIPTION

- Have** a second pregnancy test 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 REMS and confirm your 2 forms of birth control
 - **Note: you can answer your comprehension questions only after your doctor/prescriber has entered your pregnancy test result in the iPLEDGE REMS website**
- Obtain** your prescription for no more than 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 (allowable timeframe), counting the date of specimen collection for the pregnancy test as DAY 1
 - If you are not able to obtain your first prescription within the 7-day prescription window (allowable timeframe), you will be required to wait a minimum of 19 days before you can start this process again
- Use 2** effective forms of birth control together all the time
- Keep** your appointments every month to get a prescription

DURING TREATMENT

- Use 2** effective forms 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 forms of birth control by entering them into the iPLEDGE REMS website
- Answer** different questions each month about the iPLEDGE REMS
 - **Note: you can answer your comprehension questions only after your doctor/prescriber has entered your pregnancy test result in the iPLEDGE REMS website**
- Obtain** your prescription for no more than a 30-day supply
- Obtain** your prescription within the 7-day prescription window (allowable timeframe) counting the date of specimen collection for the pregnancy test as DAY 1
 - If you do not obtain your prescription within the 7-day prescription window (allowable timeframe), 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 REMS website
- Continue** using your 2 forms 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 REMS website

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