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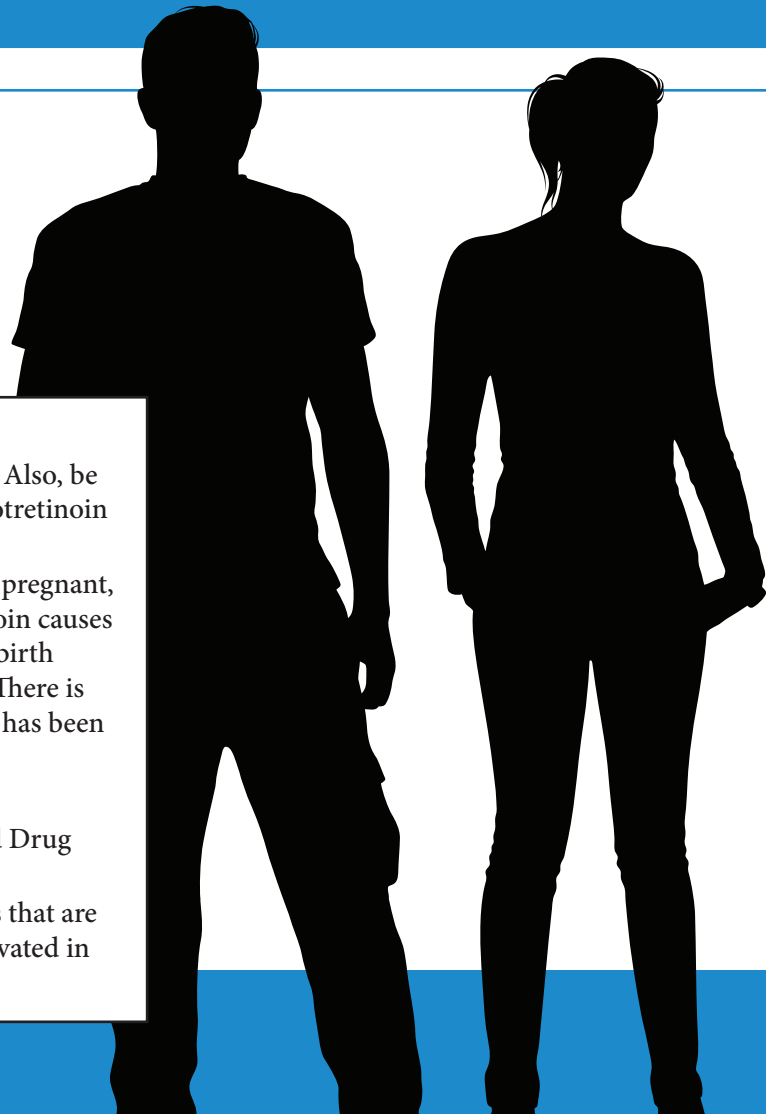
iPLEDGE[®]
Committed to Pregnancy Prevention

The iPLEDGE Program



Isotretinoin Educational Kit for Male Patients and Female Patients Who Cannot Get Pregnant

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



WARNING

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

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

IMPORTANT NOTICE

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

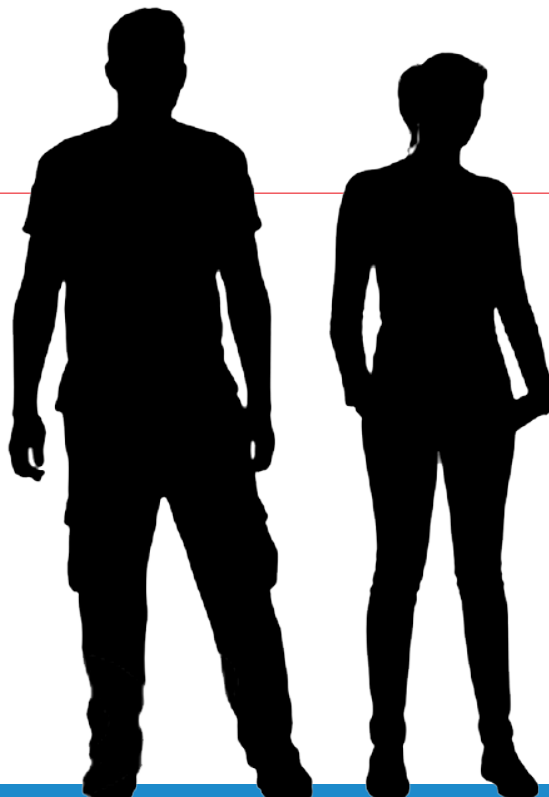
Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.



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*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.





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 Male Patients And Female Patients Who Cannot Get Pregnant Need To Know?

You can only obtain isotretinoin if:

- You are registered in the iPLEDGE® Program, your doctor/prescriber has entered your patient information in the iPLEDGE Program system, and you have your patient ID number.
- You must obtain the prescription within the 30-day prescription window, counting the office visit as DAY 1. The 30-day prescription window expires at 11:59 p.m. Eastern Time on Day 30 of the prescription window.

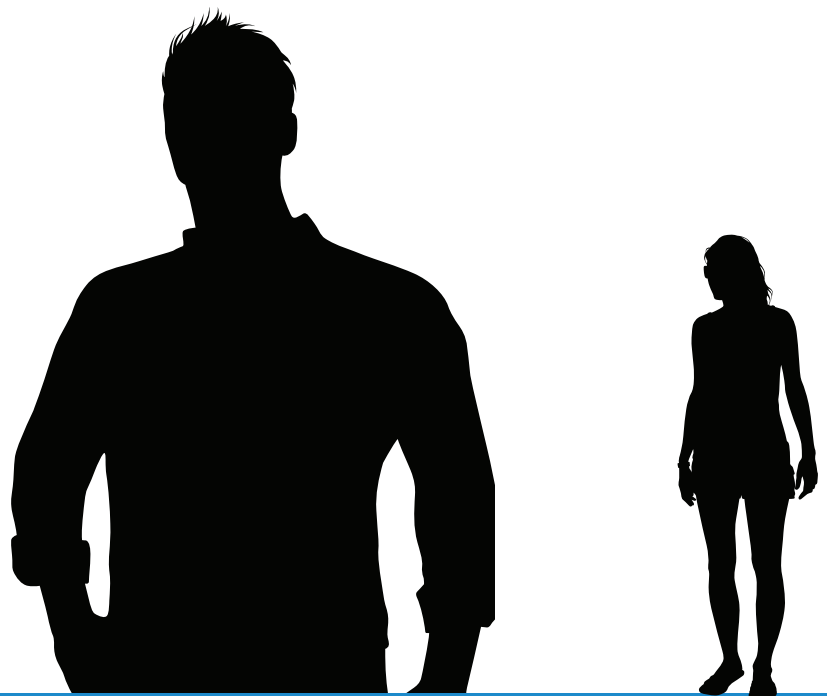
The iPLEDGE Program system will automatically compute the “Do Not Dispense To Patient After” date for your pharmacist.

To figure out the last date you can obtain your prescription, add 29 days to the date of your office visit. For example:

**Day 1
and Day of the office visit**
(Friday, March 1)

Day 2 – Day 29
(Saturday, March 2 thru
Friday, March 29)

**Day 30 – Last day to
obtain prescription**
(Saturday, March 30)



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



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.
- Registration**—ensure your doctor/prescriber registers you in the iPLEDGE Program.
- 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.

PRESCRIPTION

- 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 using your iPLEDGE Program patient ID number within the 30-day prescription window counting your office visit as DAY 1.

DURING TREATMENT

- Keep** your appointments every month to get a prescription.
- Obtain** your prescription using your iPLEDGE Program patient ID number within the 30-day prescription window counting the office visit as DAY 1. If you do not obtain your prescription within the 30-day prescription window, you will be required to start the process over again by visiting your doctor/prescriber.
- DO NOT donate** blood.

AFTER TREATMENT

- DO NOT share any leftover isotretinoin with anyone.**
- DO NOT donate** blood for 1 month after your last dose.

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

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.

See the *Safety Information About Isotretinoin* inside back pocket for more detailed information about other serious side effects, precautions, and warnings for isotretinoin.

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.





NOTES:



Patient Information/Informed Consent

Important form 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.

Safety Information About Isotretinoin

Important information you should know about isotretinoin.



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.**



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>	<h3>Duplicate ID Card</h3> <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>		<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 	<ul style="list-style-type: none"> • 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>	<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 	<ul style="list-style-type: none"> • 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>