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Committed to Pregnancy Prevention

The iPLEDGE Program
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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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
- prevent pregnant females from taking isotretinoin

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

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...
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 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 website, www.ipledgeprogram.com, has a list of registered 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 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)

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.
   t 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.

Changing to a New Doctor/Prescriber
You can change your doctor/prescriber through the iPLEDGE® Program 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.

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: