



What Is The iPLEDGE Program?

To avoid serious risks to unborn babies (fetus), 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 REMS (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 patients taking isotretinoin
- Prevent pregnant patients 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 by their prescriber in the iPLEDGE Program and agree to follow the requirements.

Indications for Isotretinoin Use

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 is a capsule you take by mouth. Treatment usually lasts 4 to 5 months. Isotretinoin can cause serious side effects, including birth defects. If a patient becomes pregnant while taking isotretinoin, there is a very high chance of birth defects. You should also learn about the side effects, precautions and warnings.

Safety Information

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 are no accurate means of determining whether a fetus exposed to isotretinoin has been affected.

Patient Identification Number

Upon completing your registration into the iPLEDGE Program, you will receive your iPLEDGE ID that includes a QR code by your preferred method of communication. Your prescriber will also write your ID number on your consent form. Take your ID along with your prescription to the pharmacy (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 Program profile, and, if required, complete your Monthly Comprehension Questionnaire.

Where can I find more information on the iPLEDGE Program?

To get information about the iPLEDGE Program, you should talk to your doctor or visit the iPLEDGE Program website www.ipledgeprogram.com.

