



What is Isotretinoin?

Isotretinoin capsules are prescription medicines used in patients 12 years of age and older, who are not pregnant, for the treatment of severe acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Isotretinoin capsules can cause serious side effects. Isotretinoin capsules can only be:

- prescribed by healthcare providers enrolled in the iPLEDGE REMS
- dispensed by pharmacies enrolled in the iPLEDGE REMS
- given to patients enrolled in the iPLEDGE REMS who agree to do everything required in the program

It is not known if isotretinoin capsules are safe and effective in children less than 12 years of age.

What are the most serious risks of Isotretinoin?

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

Isotretinoin may cause depression, psychosis (seeing or hearing things that are not real), and or 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 signs and symptoms of depression or psychosis.

What is the iPLEDGE REMS?

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

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 by their prescriber in the iPLEDGE REMS and agree to follow the requirements.

What do I need to do to enroll in the iPLEDGE REMS?

Talk with your doctor about isotretinoin and the iPLEDGE REMS. Review the educational materials provided by your prescriber. Your prescriber will then enroll you into the iPLEDGE REMS once all REMS requirements are met and you have verified understanding of these materials by signing the consent(s) during the enrollment process.

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, if required, complete your Monthly Comprehension Questionnaire.

Where can I find more information on the iPLEDGE REMS?

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

