

Isotretinoin

Medicine for severe acne

What do I need to know about isotretinoin?

- For you to receive isotretinoin, you, your doctor, and your pharmacy must be registered in the iPLEDGE program.
- Do **not** give blood while taking isotretinoin. Wait 30 days after completing treatment to give blood. This avoids exposing pregnant women to isotretinoin through your donated blood.



Talk with your pharmacist or doctor if you have questions about isotretinoin.

How do I get refills?

- You cannot get more than a 30-day supply of isotretinoin at a time. If you want a refill after 30 days, you must see your doctor or provider for a new prescription. They will check on your progress and ask about side effects.
- You must fill your prescription within 7 days of being confirmed in the iPLEDGE program.

Are there any side effects?

- You may have a flare in your acne during your first treatment period.
- Some people may become depressed or develop serious mental problems while taking isotretinoin or soon after stopping. Stop taking isotretinoin if you feel depressed or have thoughts of violence or suicide. Call your doctor **right away** if you have these symptoms.
- Isotretinoin can increase your cholesterol and triglyceride levels and decrease your HDL (the “good” cholesterol) levels. Your healthcare provider will monitor these levels. If needed, your provider will advise therapy, including changes in diet or prescription drugs.
- Alcohol can increase your risk of high cholesterol or high blood lipids. While you are taking isotretinoin, limit how much alcohol you drink:
 - Men: Do not drink more than 1 to 2 alcoholic drinks a day
 - Women: Do not drink more than 1 alcoholic drink a day

“1 drink” is equal to:

- 12 ounces of beer (light beer is best)
 - 4 ounces of wine
 - 2 ounces of dry sherry
 - 1½ ounces of distilled spirits such as whiskey, rye, vodka, or gin
- If you wear contact lenses, they may feel uncomfortable while you are taking isotretinoin. If your eyes feel dry, talk with your eye doctor.
 - Isotretinoin may decrease your night vision or cause other changes in vision. If you have any change in vision, stop taking this medicine and see your eye doctor.
 - Isotretinoin can make you more sensitive to the sun. Avoid being out in the sun if possible, especially when it is hot. If you must be in the sun, wear protective clothing and use sunscreen. Do not use sun lamps or tanning beds or booths.
 - While you are taking isotretinoin, and for at least 6 months after you stop, avoid waxing for hair removal and other cosmetic procedures to smooth your skin. This means no dermabrasion or laser therapy. There is a high risk of having scarring if you have these procedures while isotretinoin is in your body. Ask your healthcare provider when it will be OK to have cosmetic procedures.

Females:

- Isotretinoin can cause birth defects. Do not get pregnant while you are taking it. Severe birth defects may occur, even if only 1 dose is taken.
- You will need to have 2 negative pregnancy tests before starting isotretinoin. You must have monthly pregnancy tests during treatment, even if you are not sexually active.
- Use 2 reliable forms of birth control together for 1 month before, during, and for 1 month after stopping isotretinoin. Do **not** use birth control pills that do not contain estrogen. They may not work while you are taking isotretinoin.
- If you become pregnant, miss a menstrual cycle, or stop using birth control, you must stop taking isotretinoin **right away**. If you are pregnant, you must report it to 2 places:
 - FDA MedWatch, 800.FDA.1088
 - iPLEDGE pregnancy registry, 866.495.0654
- Do not breastfeed while taking isotretinoin. Wait for 1 month after stopping treatment before you start breastfeeding.

Questions?

Your questions are important. Talk with your healthcare provider if you have questions or concerns.