



Gary Mendese, MD
Stephen Moyer, DO
Robert Murgia, DO
Daniel O'Connor, MD
Neera Nathan, MD
Molly Plovanych, MD

Heather Bigos, PA-C
Rachel York, PA-C
Nathan Hand, PA-C
Brittany Smith, PA-C
Emily Rush, PA-C
Stephanie Grant, NP

Jane Tallent, NP
Lindsey MacMillan, NP
Carly Dobbie, NP
Lindsey Ramsey, RN
Brooke Comire, RN

ISOTRETINOIN

What Is Isotretinoin?

Isotretinoin is an oral prescription medication that treats severe acne. Treatment usually last 4-6 months but can take longer.

What Should I Tell my Doctor Before Taking Isotretinoin?

Tell your doctor if you or a family member has any of the following health conditions:

- Mental Health Conditions
- Asthma
- Liver disease
- Diabetes
- Heart disease
- Bone loss/ osteoporosis
- Food or Medication Allergies
- Bowel disease like Crohn's or Ulcerative Colitis.

Tell your doctor if you are pregnant or breastfeeding. Women who are pregnant or breastfeeding must not use isotretinoin.

Tell your doctor about all medications you are taking including prescription and nonprescription medications, vitamins and supplements. Isotretinoin and certain medications can interact with each other, sometimes causing serious side effects.

How Should I take Isotretinoin?

You must take isotretinoin exactly as prescribed. You must also follow all the instructions of the Ipledge program. Before prescribing isotretinoin, your provider will:

- Explain the Ipledge program in detail
- Have you sign the Patient Information/Informed Consent (for all patients). Female patients of Reproductive Potential must also sign another consent form.

You will not be prescribed isotretinoin if you cannot agree to or follow all the instructions of the Ipledge program.

- You will not receive more than a 30-day supply of isotretinoin at a time. This is to make sure you are following the Ipledge program. This is a Federal requirement.



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- The amount of isotretinoin you take has been specifically chosen for you. It is based upon your body weight and may change during treatment.
- If you miss a dose, just skip the dose. Do not take 2 doses at the same time.
- Your acne may get worse when you first start taking isotretinoin. This should only last a short while.
- You must continue with monthly follow up visits while on isotretinoin. You may also need to periodically have your blood drawn during your treatment course to monitor of potential side effects. Female patients who can get pregnant will have a pregnancy test each month.
- Females patient who can get pregnant must agree to use 2 separate methods of effective birth control at the same time 1 month before, while taking and 1 month after taking isotretinoin
 - You must access the Ipledge program system to answer questions about the program requirements and to enter your 2 methods of birth control. You will not be able to receive your medication unless you perform this action each month. This is a Federal requirement.

What Should I Avoid While Taking Isotretinoin?

- Do not get pregnant while taking isotretinoin and for 1 month after stopping isotretinoin.
- Do not breastfeed while taking isotretinoin and for 1 month after stopping isotretinoin. We do not know if the medication can pass through your milk and harm the baby.
- Do not give blood while taking this medication and for 1 month after completing isotretinoin.
- Avoid elective procedures while on isotretinoin. Isotretinoin can potentially interfere with the healing process.
- Avoid sunlight and ultraviolet lights as much as possible. Isotretinoin can make you more sensitive to light.
- Do not share isotretinoin with other people.



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What Are The Possible Side Effects of Isotretinoin?

The common, less serious side effects of isotretinoin are dry skin, chapped lips, dry eyes, and dry nose that may lead to nose bleeds.

- Isotretinoin can cause birth defects, loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.
- **Lab Abnormalities.** Sometimes isotretinoin can temporarily affect liver enzymes. Less common is decreased red and white blood cells. This is typically monitored with blood work.
- **Mental health Issues.** Isotretinoin may be associated with:
 - Depression
 - Psychosis (seeing or hearing things that are not real)
 - Suicide. Some patients taking isotretinoin have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts).
- **Serious brain problems.** Isotretinoin can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking isotretinoin and call your doctor right away if you get any of these signs of increased brain pressure:
 - Bad headache
 - Blurred vision
 - Dizziness
 - Nausea or vomiting
 - Seizures (convulsions)
 - Stroke
- **Skin problems.** Dry skin, especially on the lips is a very common occurrence while on isotretinoin. Skin rash can occur in patients taking isotretinoin. In some patients a rash can be serious. Stop using isotretinoin and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like "pinkeye"), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **GI Issues.** Call your provider if you have unexplained stomach pain or blood in your stool.



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- **Bone and muscle problems.** Although rare isotretinoin may affect bones, muscles, and ligaments and cause pain in your joints or muscles. Tell your doctor if you plan hard physical activity during treatment with isotretinoin. Tell your doctor if you get:
 - Backpain
 - Joint pain
 - A broken bone
 - Tell all healthcare providers that you take isotretinoin if you break a bone
- **Allergic reactions.** Stop taking isotretinoin and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking isotretinoin and call your doctor if you get a fever, rash, red patches or bruises on your legs.

These are not all of the possible side effects with isotretinoin. Call your doctor if you get any side effect that bothers you or that does not go away.