

Isotretinoin (Accutane) and iPledge

What is Isotretinoin?

- Isotretinoin (brand name: Accutane) is an oral retinoid that is used to treat moderate to severe acne and other dermatologic conditions.
- Treatment typically lasts 4-8 months but may last longer depending on severity, clinical progress, and body weight.
- The cumulative total dose over a prolonged period of time is what ultimately results in improvement of acne. It is important to take it as prescribed and not to take more than instructed.
- Due to the nature of the medication and the monitoring required, you will need to be seen for monthly visits every 30-39 days and will need to complete bloodwork every 1-2 months as required by your prescribing provider.

Potential Side Effects

There are several known potential side-effects when taking isotretinoin. For this reason, patients can only receive a prescription for the medication if they are enrolled in the iPledge program to monitor. Not everyone experiences these side effects. However it is important to be aware of and understand them. If you begin experiencing any of these side effects be sure to inform your prescribing provider.

Known Common Side Effects:

The common side effects listed below can be discussed during your regularly scheduled visits.

- **Dryness of the skin, eyes, nose, and lips** – This is the most common side effect seen. Nosebleeds may occur due to dryness of the nose.
 - **Manage by:** using Vaseline or Aquaphor on your lips and inside your nose to keep it moist; using saline eye drops and warm compresses to help eye irritation; sleeping with a humidifier; moisturizing full body with a thick, bland cream (i.e. Vanicream); using only a gentle facial cleanser and body soap.
- **Joint or muscle aches** – Inform us if the pain is severe, worsening, or does not resolve with management.
 - **Manage by:** taking ibuprofen as needed for discomfort; easing into physical activity
- **Headaches** – Mild, transient headaches are normal.
 - **Manage by:** taking ibuprofen as needed
 - Note: If you are experiencing severe headaches or headaches accompanied with vision changes, nausea, vomiting, or ringing in your ears, **discontinue the medication and let us know immediately** as isotretinoin can rarely cause a dangerous increase in pressure on the brain. This is *rare* but requires serious consideration.
- **Sunburn more easily**
 - **Manage by:** wearing SPF 30+ daily and reapplying regularly; seeking shade whenever possible; wearing a broad-brimmed hat (3" or more)
 - Do not use tanning beds.
- **Temporary hair thinning** – this usually resolves after treatment.

- **Lab abnormalities** – blood work will be monitored during treatment to watch for an increase in liver enzymes, cholesterol, and triglyceride levels or a potential decrease in red and white blood cells.

Known Severe Side Effects:

The severe side effects listed below should be reported immediately by calling our office at (805) 770-3999.

- **Birth defects** – Isotretinoin results in a high rate of birth defects, miscarriage, premature birth, and infant mortality if you are or become pregnant while taking the medication. It is critical to **not** get pregnant during the course of treatment or for 1 month after completion of treatment.
 - **Manage by:** If you are someone who can become pregnant you will need to take 2 pregnancy tests dated 30-39 days apart **before** beginning treatment. You will also need to take a pregnancy test every month while taking isotretinoin, and a final pregnancy test 1 month after completing your isotretinoin treatment. Patients who can become pregnant will be required to report 2 methods of birth control while taking isotretinoin.
- **Psychiatric changes** – Isotretinoin is associated with increased levels of depression/suicidal thoughts. Recent large studies have *not* shown a definitive link, but we take this potential side effect very seriously. Please let us know if you have a personal or family history of depression or if you begin to experience any changes in your mood.
- **Inflammatory bowel disease (ulcerative colitis or Crohn's disease)** – Isotretinoin can worsen or flare these conditions. It is unknown if it may “unmask” these conditions in someone or cause it, although recent studies have *not* been able to prove a causal link. If you develop severe abdominal pain or cramping, lethargy, fever, or bloody diarrhea, we must discontinue the medication.

Note: While taking isotretinoin, your acne may get worse before it gets better at the beginning of your treatment. Rarely, isotretinoin can cause severe worsening of your acne resulting in non-healing spots, oozing, or large, painful cysts. If this occurs, we may need to discontinue the medication and treat with oral steroids and/or oral antibiotics to calm down the inflammation.

iPledge and Expectations

Patients are required to enroll in the Federal Drug Administration (FDA) program iPledge which regulates and monitors the use of isotretinoin due to the risk of severe birth defects. **All patients, even those who cannot become pregnant, must enroll in iPledge to receive a prescription for isotretinoin.**

iPledge requires timeliness and correct completion of a comprehension questionnaire every month in order for your next prescription to be released at the pharmacy. As such, **you will be required to have an appointment with your prescribing provider every 30-39 days to monitor progress, side effects, and lab work.**

For all patients

- Be sure to have lab work completed 4-5 days before each appointment whenever ordered

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- If you are having a telehealth appointment make sure to email all pictures of areas affected by acne and completed pregnancy test as applicable to **nurse@sbskin.com** either the night before or morning of your appointment
 - For face, send pictures from straight on and from both profiles
 - Include the lot number and expiration date of the pregnancy test in the photo
- Schedule each follow up appointment to be in 30-39 days
- Once isotretinoin prescription is sent, there is a **strict 7 day window to complete your iPledge comprehension questionnaire online and pick up your prescription from the pharmacy**

For patients who cannot get pregnant:

- First appointment for isotretinoin:
 - Enroll in iPledge – Complete form in office and wait for activation email
 - Order lab work – Complete as soon as possible and make sure results are sent to our office
- Once labs are received and reviewed:
 - We will confirm you in iPledge and send your prescription
 - You should schedule your next appointment in 30-39 days

For patients who can get pregnant:

- First appointment for isotretinoin:
 - Enroll in iPledge – Complete form in office and wait for activation email
 - Order lab work – Complete as soon as possible and make sure results are sent to our office
 - Take your first pregnancy test in office
 - Provide 2 methods of contraception to report for iPledge – Every month you will be required to enter these 2 methods in the same order, be sure to note them down
 - Schedule your next appointment to be in 30-39 days
- Second appointment for isotretinoin:
 - If in office, take your second pregnancy test
 - We will confirm you in iPledge and send your prescription
 - Schedule your next appointment to be in 30-39 days

What to Avoid While on Isotretinoin

- Alcohol
- Tylenol
- Tetracycline class of antibiotics (i.e. doxycycline, minocycline, tetracycline)
- Vitamin A supplements or multivitamins containing vitamin A
- Any topical acne treatments – Use only gentle skin care products
- Do not donate blood while you are on isotretinoin or for 6 months afterwards
- Avoid cosmetic procedures (facials, lasers, dermabrasion), tattoos, piercings, waxing, and electrolysis while you are on isotretinoin or for 6 months afterwards.

For more information, visit www.ipledgeprogram.com/#Main/Resources