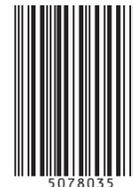


MEDICATION GUIDE
SOTRET®
(Isotretinoin Capsules, USP)



Read the Medication Guide that comes with Sotret before you start taking it and each time you get a prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Sotret?

- Sotret is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Sotret can cause birth defects, Sotret is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE program.
- Sotret may cause serious mental health problems.

1. Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. Female patients who are pregnant or who plan to become pregnant must not take Sotret. **Female patients must not get pregnant:**

- for 1 month before starting Sotret
- while taking Sotret
- for 1 month after stopping Sotret.

If you get pregnant while taking Sotret, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- the iPLEDGE pregnancy registry at 1-866-495-0654

2. Serious mental health problems. Sotret may cause:

- **depression**
- **psychosis** (seeing or hearing things that are not real)
- **suicide.** Some patients taking Sotret 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 Sotret and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms of depression or psychosis:

- start to feel sad or have crying spells
- lose interest in activities you once enjoyed
- sleep too much or have trouble sleeping
- become more irritable, angry, or aggressive than usual (for example, temper outbursts, thoughts of violence)
- have a change in your appetite or body weight
- have trouble concentrating
- withdraw from your friends or family
- feel like you have no energy
- have feelings of worthlessness or guilt
- start having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- start acting on dangerous impulses
- start seeing or hearing things that are not real

After stopping Sotret, you may also need follow-up mental health care if you had any of these symptoms.

What is Sotret?

Sotret is a medicine taken by mouth to treat the most severe form of acne (nodular acne) that cannot be cleared up by any other acne treatments, including antibiotics. Sotret can cause serious side effects (see “**What is the most important information I should know about Sotret?**”). Sotret can only be:

- prescribed by doctors that are registered in the iPLEDGE program
- dispensed by a pharmacy that is registered with the iPLEDGE program
- given to patients who are registered in the iPLEDGE program and agree to do everything required in the program

What is severe nodular acne?

Severe nodular acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger. If untreated, nodular acne can lead to permanent scars.

Who should not take Sotret?

- **Do not take Sotret if you are pregnant, plan to become pregnant, or become pregnant during Sotret treatment.** Sotret causes severe birth defects. See “**What is the most important information I should know about Sotret?**”
- **Do not take Sotret if you are allergic to anything in it.** Sotret contains **parabens** as the preservative. See the end of this Medication Guide for a complete list of ingredients in Sotret.

What should I tell my doctor before taking Sotret?

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

- mental problems
- asthma
- liver disease
- diabetes
- heart disease
- bone loss (osteoporosis) or weak bones
- an eating problem called anorexia nervosa (where people eat too little)
- food or medicine allergies

Tell your doctor if you are pregnant or breastfeeding. Sotret must not be used by women who are pregnant or breastfeeding.

Tell your doctor about all of the medicines you take including prescription and non-prescription medicines, vitamins and herbal supplements. Sotret and certain other medicines can interact with each other, sometimes causing serious side effects. Especially tell your doctor if you take:

- **Vitamin A supplements.** Vitamin A in high doses has many of the same side effects as Sotret. Taking both together may increase your chance of getting side effects.
- **Tetracycline antibiotics.** Tetracycline antibiotics taken with Sotret can increase the chances of getting increased pressure in the brain.
- **Progestin-only birth control pills (mini-pills).** They may not work while you take Sotret. Ask your doctor or pharmacist if you are not sure what type you are using.
- **Dilantin (phenytoin).** This medicine taken with Sotret may weaken your bones.
- **Corticosteroid medicines.** These medicines taken with Sotret may weaken your bones.
- **St. John's Wort.** This herbal supplement may make birth control pills work less effectively.

These medicines should not be used with Sotret unless your doctor tells you it is okay.

Know the medicines you take. Keep a list of them to show to your doctor and pharmacist. Do not take any new medicine without talking with your doctor.

How should I take Sotret?

- You must take Sotret exactly as prescribed. You must also follow all the instructions of the iPLEDGE program. Before prescribing Sotret, your doctor will:
 - explain the iPLEDGE program to you
 - have you sign the Patient Information/Informed Consent (for all patients). Female patients who can get pregnant must also sign another consent form.**You will not be prescribed Sotret if you cannot agree to or follow all the instructions of the iPLEDGE program.**
- You will get no more than a 30-day supply of Sotret at a time. This is to make sure you are following the Sotret iPLEDGE program. You should talk with your doctor each month about side effects.
- The amount of Sotret you take has been specially chosen for you. It is based on your body weight, and may change during treatment.
- Take Sotret 2 times a day with a meal, unless your doctor tells you otherwise. **Swallow your Sotret capsules whole with a full glass of liquid. Do not chew or suck on the capsule.** Sotret can hurt the tube that connects your mouth to your stomach (esophagus) if it is not swallowed whole.
- If you miss a dose, just skip that dose. Do **not** take 2 doses at the same time.
- If you take too much Sotret or overdose, call your doctor or poison control center right away.
- Your acne may get worse when you first start taking Sotret. This should last only a short while. Talk with your doctor if this is a problem for you.
- You must return to your doctor as directed to make sure you don't have signs of serious side effects. Your doctor may do blood tests to check for serious

side effects from Sotret. Female patients who can get pregnant will get a pregnancy test each month.

- Female patients who can get pregnant must agree to use 2 separate forms of effective birth control at the same time 1 month before, while taking, and for 1 month after taking Sotret. **You must access the iPLEDGE system to answer questions about the program requirements and to enter your 2 chosen forms of birth control.** To access the iPLEDGE system, go to www.ipledgeprogram.com or call 1-866-495-0654.

You must talk about effective birth control methods with your doctor or go for a free visit to talk about birth control with another doctor or family planning expert. Your doctor can arrange this free visit, which will be paid for by the company that makes Sotret.

If you have sex at any time without using 2 forms of effective birth control, get pregnant, or miss your expected period, stop using Sotret and call your doctor right away.

What should I avoid while taking Sotret?

- **Do not get pregnant** while taking Sotret and for 1 month after stopping Sotret. See “**What is the most important information I should know about Sotret?**”
- **Do not breast feed** while taking Sotret and for 1 month after stopping Sotret. We do not know if Sotret can pass through your milk and harm the baby.
- **Do not give blood** while you take Sotret and for 1 month after stopping Sotret. If someone who is pregnant gets your donated blood, her baby may be exposed to Sotret and may be born with birth defects.
- **Do not take other medicines or herbal products** with Sotret unless you talk to your doctor. See “**What should I tell my doctor before taking Sotret?**”
- **Do not drive at night until you know if Sotret has affected your vision.** Sotret may decrease your ability to see in the dark.
- **Do not have cosmetic procedures to smooth your skin, including waxing, dermabrasion, or laser procedures, while you are using Sotret and for at least 6 months after you stop.** Sotret can increase your chance of scarring from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines use ultraviolet lights. Sotret may make your skin more sensitive to light.
- **Do not share Sotret with other people.** It can cause birth defects and other serious health problems.

What are the possible side effects of Sotret?

- **Sotret can cause birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births.** See “**What is the most important information I should know about Sotret?**”
- **Sotret may cause serious mental health problems.** See “**What is the most important information I should know about Sotret?**”
- **serious brain problems.** Sotret can increase the pressure in your brain. This can lead to permanent loss of eyesight and, in rare cases, death. Stop taking Sotret 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.** Skin rash can occur in patients taking Sotret. In some patients a rash can be serious. Stop using Sotret and call your doctor right away if you develop conjunctivitis (red or inflamed eyes, like “pink eye”), a rash with a fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel.
- **stomach area (abdomen) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Sotret. Stop taking Sotret and call your doctor if you get:
 - severe stomach, chest or bowel pain
 - trouble swallowing or painful swallowing
 - new or worsening heartburn
 - diarrhea
 - rectal bleeding
 - yellowing of your skin or eyes
 - dark urine
- **bone and muscle problems.** Sotret 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 Sotret. Tell your doctor if you get:
 - back pain
 - joint pain
 - broken bone. Tell all healthcare providers that you take Sotret if you break a bone.

Stop Sotret and call your doctor right away if you have muscle weakness. Muscle weakness with or without pain can be a sign of serious muscle damage.

Sotret may stop long bone growth in teenagers who are still growing.

- **hearing problems.** Stop using Sotret and call your doctor if your hearing gets worse or if you have ringing in your ears. Your hearing loss may be permanent.
- **vision problems.** Sotret may affect your ability to see in the dark. This condition usually clears up after you stop taking Sotret, but it may be permanent. Other serious eye effects can occur. Stop taking Sotret and call your doctor right away if you have any problems with your vision or dryness of the eyes that is painful or constant. If you wear contact lenses, you may have trouble wearing them while taking Sotret and after treatment.
- **lipid (fats and cholesterol in blood) problems.** Sotret can raise the level of fats and cholesterol in your blood. This can be a serious problem. Return to your doctor for blood tests to check your lipids and to get any needed treatment. These problems usually go away when Sotret treatment is finished.
- **serious allergic reactions.** Stop taking Sotret and get emergency care right away if you develop hives, a swollen face or mouth, or have trouble breathing. Stop taking Sotret and call your doctor if you get a fever, rash, or red patches or bruises on your legs.
- **blood sugar problems.** Sotret may cause blood sugar problems including diabetes. Tell your doctor if you are very thirsty or urinate a lot.
- **decreased red and white blood cells.** Call your doctor if you have trouble breathing, faint, or feel weak.
- **The common, less serious side effects of Sotret** are dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if you get any side effect that bothers you or that does not go away.

These are not all of the possible side effects with Sotret. Your doctor or pharmacist can give you more detailed information. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

How should I store Sotret?

- Store Sotret at 20 - 25° C (68 - 77° F) [See USP Controlled Room Temperature]. Protect from light.
- **Keep Sotret and all medicines out of the reach of children.**

General Information about Sotret

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use Sotret for a condition for which it was not prescribed. Do not give Sotret to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Sotret. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Sotret that is written for health care professionals. You can also call iPLEDGE program at 1-866-495-0654 or visit www.ipledgeprogram.com.

What are the ingredients in Sotret?

Active Ingredient: Isotretinoin.

Inactive Ingredients: butylated hydroxyanisole, edetate disodium, hydrogenated soybean oil, hydrogenated vegetable oil, iron oxide black, soybean oil and white wax. Gelatin capsules contain glycerin and parabens (methyl and propyl), with the following dye systems: 10 mg - iron oxide (red) and titanium dioxide; 20 mg - FD&C Red No. 3, FD&C Blue No. 1, and titanium dioxide; 30 mg - FD&C Yellow No. 6, and titanium dioxide; 40 mg - FD&C Yellow No. 6, D&C Yellow No. 10, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Dilantin is a registered trademark of Warner-Lambert Company LLC.

Manufactured for:
Ranbaxy Laboratories Inc.
Jacksonville, FL 32257 USA
by: Ranbaxy Laboratories Limited
New Delhi -110 019, India
February 2010

5078035

Size: 216 x 356 mm

Font Size: 10 Pt.

Track: R18/02/10, R25/02/10, R02/03/10, R08/03/10