

Patient Information

Bexarotene (bek-sar'ah-tēn) Capsules

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

Bexarotene can cause serious side effects, including major birth defects to an unborn baby, if taken during pregnancy.

For females who can become pregnant:

- **You should avoid becoming pregnant during treatment with bexarotene.**
- **Do not take bexarotene if you are pregnant or plan to become pregnant.**
- Your healthcare provider will do a pregnancy test, within one week before you start bexarotene, and each month during treatment with bexarotene to make sure that you are not pregnant.
- **You must use two effective forms of birth control together starting one month before you begin treatment with bexarotene, during treatment, and for one month after stopping bexarotene.** Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used with bexarotene. At least one of the forms of birth control that you choose should not contain hormones. Talk to your healthcare provider about what forms of birth control may be right for you during treatment with bexarotene.
- **You should start taking bexarotene on the second or third day of a normal menstrual period.** Follow your healthcare provider's instructions about when to start bexarotene.
- Call your healthcare provider right away, if you become pregnant or think that you are pregnant during treatment with bexarotene, and for one month after you stop taking bexarotene.

For males:

- You must use a condom with female partners who are pregnant, might be pregnant, or who are able to become pregnant, during treatment with bexarotene and for at least one month after your last dose.

What is bexarotene?

Bexarotene is a prescription medicine used to treat the skin problems that happen with a type of cancer called cutaneous T-cell lymphoma (CTCL) after treatment with at least one other type of medicine by mouth or injection, did not work or has stopped working.

It is not known if bexarotene is safe and effective in children.

Who should not take bexarotene?

Do not take bexarotene:

- if you are pregnant or plan to become pregnant. See "**What is the most important information I should know about bexarotene?**"
- if you are allergic to any of the ingredients in bexarotene. See the end of this leaflet for a complete list of ingredients in bexarotene.

Before taking bexarotene, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had problems with your pancreas, including pancreatitis
- have or have had gallbladder problems
- have or have had liver problems
- have thyroid problems
- have diabetes
- have high levels of fats (lipids) called cholesterol or triglycerides in your blood
- have cataracts or a history of cataracts
- drink alcohol
- are pregnant, plan to become pregnant, or think you may be pregnant. See "**What is the most important information I should know about bexarotene?**"
- are breastfeeding or plan to breastfeed. It is not known if bexarotene passes into your breast milk. You should not breastfeed during treatment with bexarotene. Talk to your healthcare provider about the best way to feed your baby during treatment with bexarotene.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using bexarotene with certain other medicines can affect each other.

How should I take bexarotene?

- Take bexarotene exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many bexarotene capsules to take each day. Your healthcare provider may change your daily dose of bexarotene as needed to treat your CTCL or if you get certain side effects. You should not change your dose unless your healthcare provider tells you to.

Take your dose of bexarotene 1 time a day with a meal. Your healthcare provider will do blood tests before you start bexarotene and during treatment to check for side effects.

What should I avoid while taking bexarotene?

- Limit your exposure to sunlight and artificial types of sunlight. Bexarotene can make your skin more sensitive to sunlight and you can get sunburn.
- Limit the amount of vitamin A that you take during treatment with bexarotene. Large doses of vitamin A may cause side effects that are similar to side effects that can happen in people who take bexarotene.

What are the possible side effects of bexarotene?

Bexarotene can cause serious side effects, including:

- See "**What is the most important information I should know about bexarotene?**"
- **Increased levels of fats (lipids) called cholesterol or triglycerides in your blood are common with bexarotene, but can also be serious.** Your healthcare provider may prescribe you medicines to treat high cholesterol or triglycerides levels, reduce your dose, temporarily stop treatment or completely stop treatment with bexarotene if you have this problem.

- **Inflammation of the pancreas (acute pancreatitis).**

Bexarotene can sometimes cause pancreatitis that comes on suddenly (acute), and that can lead to death. Your risk of developing acute pancreatitis may be greater if you:

- have had pancreatitis in the past
- high levels of fats in your blood that are not controlled
- drink large amounts of alcohol
- have gallbladder problems
- have diabetes that is not controlled
- take certain medicines that can increase the amount of triglycerides in your blood
- take medicines that can harm your pancreas

Tell your healthcare provider right away if you develop signs or symptoms of pancreatitis during treatment with bexarotene, including:

- nausea that will not go away
 - vomiting
 - stomach-area (abdominal) or back pain
- **Liver problems, including liver failure.** Bexarotene can cause increased liver function blood test results, or liver problems that can lead to death.
 - **Thyroid problems (hypothyroidism) are common with bexarotene.** Your healthcare provider may prescribe thyroid hormone treatment for you if needed.
 - **Low white blood cell count is common with bexarotene, but may sometimes be severe.**
 - **New or worse cataracts.** Tell your healthcare provider about any changes in your vision during treatment with bexarotene. You may need to have an eye examination.
 - **Risk of low blood sugar in people who have diabetes.** Bexarotene can interact with certain medicines used to treat diabetes, such as insulin, sulfonylurea medicines, and thiazolidinedione medicines. If you have diabetes, talk to your healthcare provider about your diabetes medicines and your risk for low blood sugar if you take bexarotene.

The most common side effects of bexarotene include:

- headache
- asthenia
- rash
- nausea
- infection
- stomach-area (abdomen) pain
- swelling of your hands, arms, feet or legs
- dry skin

These are not all the possible side effects of bexarotene. 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 bexarotene?

- Store bexarotene between 2° to 25°C (36° to 77°F).
- Store the bexarotene bottle away from light, heat, and humidity.
- The capsules should not be taken after the expiration date printed on the bottle.

Keep bexarotene and all medicines out of the reach of children.

General information about the safe and effective use of bexarotene

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use bexarotene for a condition for which it was not prescribed. Do not give bexarotene to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about bexarotene that is written for health professionals

What are the ingredients in bexarotene?

Active ingredient: bexarotene

Inactive ingredients: butylated hydroxyanisole, polyethylene glycol, polysorbate and povidone. The capsule shell contains gelatin, glycerin, sorbitol, titanium dioxide and water.

For more information, visit www.upsher-smith.com or call 1-888-650-3789.

This Patient Information has been approved by the U. S. Food and Drug Administration.

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Upsher-Smith Laboratories, LLC
Patient Information Leaflet**

Bexarotene Capsules

An FDA approved Patient Information Leaflet for Upsher-Smith's Bexarotene Capsules is available.

We offer two convenient ways to obtain Bexarotene Capsules Patient Information Leaflets:

1. Go to www.upsher-smith.com. From the "Our Products" tab, choose "Products A-Z". Click on the product name to access a printable Patient Information Leaflet.
2. Call 1-888-650-3789 from 8:00 a.m. to 5:00 p.m. CST to place an order for 1 to 3 pads of 50. Please be prepared with the address where you would like them shipped and allow 1–2 weeks for delivery.