



Bexarotene

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IMPORTANT WARNING:

Bexarotene must not be taken by patients who are pregnant or who may become pregnant. There is a high risk that bexarotene will cause the baby to be born with birth defects (problems that are present at birth).

Talk to your doctor about the risks of taking bexarotene.

For female patients:

If you can become pregnant, you will need to avoid becoming pregnant during your treatment with bexarotene. You must use two acceptable forms of birth control for 1 month before you begin to take bexarotene, at all times during your treatment, and for 1 month after your treatment. Your doctor will tell you which forms of birth control are acceptable. Bexarotene may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, and injections), so it is especially important to use a second form of birth control along with this type of contraceptive.

You will begin to take bexarotene on the second or third day of your menstrual period. You must have a negative pregnancy test within 1 week of the start of your treatment and every month during your treatment. After each negative pregnancy test, you will be given only 1 month's supply of bexarotene.

Stop taking bexarotene and call your doctor right away if you think you are pregnant, you miss a menstrual period, or you have sex without using two forms of birth control.

For male patients:

You must use a condom every time you have sexual contact with a female who is pregnant or able to become pregnant while you are taking bexarotene and for 1 month after your treatment. Call your doctor if your partner becomes pregnant during this time.

Why is this medication prescribed?

Bexarotene is used to treat cutaneous T-cell lymphoma (CTCL, a type of skin cancer) in people whose disease could not be treated successfully with at least one other medication. Bexarotene is in a class of medications called retinoids. It works by stopping the growth of cancer cells.

How should this medicine be used?

Bexarotene comes as a capsule to take by mouth. It is usually taken once a day with food. Take bexarotene at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take bexarotene exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not chew the capsules or dissolve them in liquid or in your mouth. If you are unable to swallow the capsules whole, talk to your doctor.

Bexarotene may be harmful if it gets on the skin. Do not touch the capsules or powder from the capsules if they are broken or leaking. If the powder from a broken capsule gets on your skin, wash the area with soap and water immediately and call your doctor.

Your doctor will start you on an average dose of bexarotene and may decrease your dose if you experience side effects or increase your dose if your condition does not improve.

It may take several months or longer before you notice the full benefit of bexarotene. Do not stop taking bexarotene without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking bexarotene,

- tell your doctor and pharmacist if you are allergic to bexarotene; or any other retinoid, such as acitretin (Soriatane), etretinate (Tegison), isotretinoin (Accutane), or tretinoin (Vesanoid); or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: amiodarone (Cordarone); certain antifungals such as ketoconazole (Nizoral) and itraconazole (Sporanox); cimetidine (Tagamet); clarithromycin (Biaxin); diltiazem (Cardizem); erythromycin (E.E.S., E-Mycin, Erythrocin); fluvoxamine; gemfibrozil (Lopid); HIV protease inhibitors such as indinavir (Crixivan), nelfinavir (Viracept), and ritonavir (Norvir, in Kaletra); insulin and oral medications for diabetes; nefazodone; phenobarbital; phenytoin (Dilantin); rifampin (Rifadin, Rimactane); tamoxifen (Nolvadex); verapamil (Calan); and vitamin A. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with bexarotene, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you drink or have ever drunk large amounts of alcohol. Also tell your doctor if you have or have ever had pancreatitis; high levels of cholesterol and other fatty substances in the blood; diabetes; cataracts; or gall bladder, thyroid, kidney, or liver disease.
- tell your doctor if you are breast-feeding.

- ask your doctor about the safe use of alcoholic beverages while you are taking bexarotene. Alcohol can make the side effects from bexarotene worse.
- plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, sunglasses, and sunscreen. Bexarotene may make your skin sensitive to sunlight.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose with food as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Bexarotene may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- weakness
- tiredness
- increased sensitivity to cold
- increase in weight
- depression
- joint or muscle pain
- thin, brittle hair or fingernails
- constipation
- rash
- dry skin
- redness, scaling, or itching of the skin
- hair loss
- swelling of ankles, feet, and legs
- difficulty falling asleep or staying asleep
- nausea
- vomiting
- diarrhea

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- sudden or ongoing back or stomach pain
- severe and ongoing nausea and vomiting
- fever, sore throat, chills, or other signs of infection
- changes in vision

Bexarotene may increase the levels of cholesterol and other fats in your blood and may stop your thyroid gland from working normally. Your doctor will monitor you carefully to see whether you are experiencing either of these side effects. If you experience either of these side effects, your doctor may prescribe another medication to control the side effect while you are taking bexarotene.

Bexarotene may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

What storage conditions are needed for this medicine?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat, light, and moisture (not in the bathroom). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to bexarotene.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking bexarotene.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Targretin®

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