

Targretin® (bexarotene) capsules, 75 mg Patient's Instructions for Use

To help you get the full benefits from this medicine, you should read this leaflet carefully and ask your doctor to explain anything you do not understand.

What are the most important things I should know about Targretin® capsules?

- Targretin® capsules can cause major damage to a fetus. Pregnancy must be avoided in patients receiving Targretin® capsules.
- Targretin® capsules can greatly increase blood levels of lipids (triglycerides and cholesterol) and these levels must be monitored and, if elevated, treated.
- Targretin® capsules can cause an underactive thyroid and periodic blood tests will be needed to detect this. Medication to control the condition may be necessary.

Do not take Targretin® capsules if you are pregnant or if you plan to become pregnant.

- Targretin® capsules may harm your fetus (unborn baby). You should contact your doctor immediately if you believe or suspect you are pregnant while you are taking Targretin® capsules and until one month after you stop taking Targretin® capsules.
- If you are capable of becoming pregnant, you must have a pregnancy test, within one week before you start Targretin® capsule therapy and monthly while you are taking Targretin® capsules, confirming you are not pregnant.
- You must use effective contraception (birth control) continuously starting one month before beginning treatment with Targretin® capsules until one month after you stop taking Targretin® capsules. It is strongly recommended that two reliable forms of contraception be used together. At least one of these two forms of contraception should include condoms, diaphragms, cervical caps, IUDs, or spermicides.
- If you are male and your partner is pregnant or capable of becoming pregnant, you should discuss with your doctor the precautions you should take.

What are Targretin® capsules?

Targretin (tar-GRET-in) capsules contain bexarotene (beks-AIR-oh-teen). Targretin® capsules belong to a class of medicines known as retinoids. Each off-white, oblong soft gelatin Targretin® capsule contains 75 mg of bexarotene. Each capsule is imprinted with the name “Targretin” in blue.

What are the uses for Targretin® capsules?

This medicine is used to treat the skin problems arising from a disease called cutaneous T-cell lymphoma, or CTCL. Your doctor must supervise the use of Targretin® capsules.

Do not take Targretin® capsules if you are allergic to this medicine.

If you have any of the following conditions, make sure you have discussed them with your doctor before you start to take this medicine.

- You are pregnant or think you may be pregnant.
- You have or previously had an inflamed pancreas (pancreatitis).
- You are breastfeeding.
- You are taking gemfibrozil (Lopid®)*, a medication to reduce high triglyceride cholesterol (fats) levels in the blood.
- You are taking tamoxifen (Nolvadex®)†

Medical conditions you should tell your doctor about.

- If you are allergic to retinoid medications (for example: Accutane® [isotretinoin], Soriatane® [acitretin], Tegison® [etretinate], Vesanoid® [tretinoin])‡
- If you have or ever had high triglyceride (a fatty substance) levels in your blood.
- If you have diabetes mellitus (sugar diabetes).
- If you have a history of or currently have gall bladder disease.
- If you have or have had any liver disease.
- If you regularly drink more than a small amount of alcohol.

- If you are currently taking any prescription medication especially for fungal infections, bacterial infections, or seizures.
- If you eat a lot of grapefruit or drink a lot of grapefruit juice.

When should you be extra careful while taking Targretin® capsules?

- Because vitamin A in large doses may cause some side effects which are similar to those seen in patients taking Targretin® capsules, do not take more than the recommended daily dietary allowance of vitamin A (4000 to 5000 International Units). If you take vitamins, check the label to see how much vitamin A they contain. If you are not sure, ask your doctor or pharmacist.
- Your skin may become more sensitive to sunlight while taking this medicine. Minimize exposure to sunlight and do not use a sunlamp.

How should Targretin capsules be taken?

- Always take Targretin® capsules the way your doctor tells you.
- Your doctor will tell you how many Targretin® capsules to take each day. You should take your daily dose of Targretin® capsules all at once. It is best to take them once each day with or immediately following a meal. For example, you might always take your daily amount of Targretin® capsules with your evening meal.
- Always swallow each capsule whole; do not chew them or dissolve them in liquid or in your mouth. Depending on your health and condition, your doctor may change your daily dose (the number of capsules you are taking) during your treatment.
- If you miss a dose, take it as soon as possible, with food. However, if it is nearly time for your next dose, skip the missed dose and continue your dose schedule as before. Do not take a double dose.
- If you take too many Targretin® capsules or someone else accidentally takes your medicine, contact your doctor, emergency room or the nearest hospital immediately.

How long before you can expect your CTCL to improve on Targretin® capsule treatment?

- Although some patients saw improvement within the first several weeks of Targretin® capsule treatment, most patients required several months or more of treatment to improve.

- Your doctor should determine how long you should be taking Targretin® capsules, and when treatment may be stopped.

What side effects do Targretin® capsules have?

The most common side effect is an increase in blood lipids (fats in the blood). Periodic blood tests will be needed to determine blood levels of lipids, including triglycerides and cholesterol. Medication may be needed to control high fat levels in the blood.

Another common side effect is underactive thyroid. The symptoms of underactive thyroid may be difficult to detect because they may develop very gradually and may be very mild. For example, you may begin to feel always tired, low on energy, or feeling unusually cold all the time. A thyroid hormone medication is readily available to fully control these temporary symptoms, so contact your doctor early if you feel you are beginning to experience any of these symptoms. Periodic blood tests will be needed to detect this.

When should you call your doctor about possible complications of Targretin® capsule treatment?

As an infrequent side effect of Targretin® capsule treatment, pancreatitis (inflamed pancreas) may occur. Symptoms of pancreatitis include persistent nausea, vomiting, and abdominal or back pain. If you develop any of these symptoms while taking Targretin® capsules, contact your doctor immediately.

All medications have side effects. You should call your physician regarding any questions or concerns you may have when taking Targretin® capsules.

How should Targretin® capsules be stored?

- The capsules should be stored in a dry place in a closed container, away from light and heat, at room temperature.
- The capsules should not be used after the expiration date printed on the bottle.
- Keep this medicine out of the reach and sight of children.

If Targretin® capsules are broken or leaking, do not touch the capsules or the contents and notify your pharmacist immediately. Should the contents of a

broken capsule get on your skin, immediately wash the area with soap and water and notify your physician.

Further Information

- You can get more information on Targretin® capsules from your doctor or pharmacist.

* Lipid® (gemfibrozil tablets, USP) is a registered trademark of Parke-Davis, Division of Warner-Lambert Co.

† Nolvadex® (tamoxifen citrate) is a registered trademark of AstraZeneca LP.

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