Package leaflet: Information for the user

Bexarotene 75 mg soft capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bexarotene is and what it is used for

The active substance in Bexarotene, bexarotene, belongs to a group of medicines known as retinoids, which are related to vitamin A.

Bexarotene capsules are used by patients with advanced stage cutaneous T-cell lymphoma (CTCL) whose disease has not responded to other therapies. CTCL is a condition in which certain cells of the body's lymph system called T-lymphocytes become cancerous and affect the skin.

2. What you need to know before you take Bexarotene

Do not take Bexarotene:
- if you are allergic to bexarotene or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast feeding or if you can become pregnant and are not using effective birth control measures.
- if you have a history of pancreatitis, have uncontrolled lipid (blood fats) elevations (high blood cholesterol or high blood triglycerides), have a condition known as hypervitaminosis A, have uncontrolled thyroid disease, have insufficient liver function or have an ongoing systemic infection.

Warnings and precautions

Talk to your doctor before taking Bexarotene
- if you have a known hypersensitivity to retinoids (related to vitamin A), suffer from liver disease, have high blood lipids or take medicines which may cause high blood lipids, have uncontrolled diabetes mellitus (sugar diabetes), have had gall bladder or biliary tract disease, or consume excessive amounts of alcohol.
- if you have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Bexarotene may affect your mood.

Your fasting blood lipid determinations may have to be performed before therapy is initiated and at weekly intervals afterwards, and then monthly while taking this medicine. Blood tests to evaluate the function of your liver and thyroid gland and to monitor your red blood cell and white blood cell counts will be obtained before therapy is started and will be monitored during therapy.

Periodic eye exams may be needed if you experience visual difficulties while taking this medicine.

Minimise exposure to sunlight as much as possible and avoid exposure to sun lamps.

Do not take more than 15,000 International Units of vitamin A supplements per day during treatment.

Mental health problems

You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that this medicine could affect your mood and behaviour. They may notice these changes and help you identify any problems that you need to talk to your doctor about.

Children and adolescents

Bexarotene capsules should not be used in children or adolescents.

Other medicines and Bexarotene

Tell your doctor if you are taking, have recently taken or might take any other medicines, such as
- ketoconazole and itraconazole (used against fungal infections),
- erythromycin, clarithromycin and rifampicin (used against bacterial infections),
- phenytoin and phenobarbital (used against seizures),
- gemfibrozil (used to reduce high levels of fats in the blood such as triglycerides and cholesterol),
- vitamin A supplements, protease inhibitors (used against viral infections),
- tamoxifen (used against some forms of cancer),
- dexamethasone (used for inflammatory conditions),
- insulin, agents enhancing insulin secretion, or insulin-sensitisers (used against diabetes mellitus).

This is important as using more than one medicine at the same time can strengthen or weaken the effect of the medicines.

Bexarotene with food and drink

Bexarotene should be taken with food (see section 3). If you regularly consume grapefruit or grapefruit juice, please consult your doctor as these have the potential to alter your body's response to Bexarotene therapy.

Pregnancy and breast-feeding

Bexarotene may be harmful to a developing foetus. DO NOT use Bexarotene if you are pregnant or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you are capable of becoming pregnant, you must have a pregnancy test within one week before you start therapy, confirming you are not pregnant. You must use effective contraception (birth control) continuously starting one month before beginning therapy until one month after you stop taking Bexarotene. It is recommended that two reliable forms of contraception be used together. If you are taking a hormonal contraceptive (for example, birth control pills), you should discuss this with your doctor.

If you are male and your partner is pregnant or capable of becoming pregnant, you must use condoms during sexual intercourse while taking bexarotene and for at least one month after the last dose.

Driving and using machines

It is not known whether Bexarotene has an effect on your ability to drive a car or operate machinery. If you experience dizziness or problems with your vision during therapy, do not drive or operate machinery.

Bexarotene contains sorbitol and butylated hydroxyanisole

This medicine contains 93 mg sorbitol in each capsule. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

Butylated hydroxyanisole may cause irritation to the mucous membranes, therefore the capsules must be swallowed intact and not chewed.

3. How to take Bexarotene

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The doctor will prescribe a suitable dose for you.

The recommended dose is generally 4 to 10 capsules to be taken once daily. Take your prescribed number of capsules at the same time each day with a meal. The capsules can be taken immediately before, during or immediately after the course of the meal, if preferred. The capsules should be swallowed whole and not chewed.

How long you should take Bexarotene

Although some patients have improvement within the first several weeks, most patients require several months or more of treatment to improve.

If you take more Bexarotene than you should

If you have taken more than the prescribed dose of Bexarotene, you must contact your doctor.

If you forget to take Bexarotene
If you forget to take one dose, take your daily dose with your next meal on the same day, then take your usual dose as normal, the following day. Do not take a double dose in one day to make up for a forgotten dose the previous day.

If you stop taking Bexarotene
Your doctor should determine how long you should take Bexarotene, and when treatment may be stopped. Do not stop taking your medication until your doctor advises you to do so.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor as soon as possible if you feel any deterioration in your condition while you are taking Bexarotene. Sometimes it is necessary to adjust the dose or interrupt treatment. Your doctor will advise you on what to do.

The following side effects were reported in patients with CTCL who were treated with the recommended initial dose of capsules.
Very common (can occur in more than 1 in 10 patients treated):
- Low white blood cell count.
- Lowering of thyroid hormones level.
- Elevation of blood fats (triglycerides and cholesterol).
- Skin reactions (Itching, redness, irritation, peeling).
- Headache, fatigue, pain.

Common (can occur in up to 1 in 10 patients treated):
- Low red blood cell count, enlarged lymph nodes, worsening of lymphoma.
- Thyroid disorder.
- Elevation of liver enzymes, impaired kidney function, low protein in blood, weight gain.
- Insomnia, dizziness, reduced skin sensation.
- Dry eyes, deafness, abnormal sensations of the eye including irritation and heaviness.
- Swelling of legs and arms.
- Nausea, diarrhoea, dry mouth, dry lips, loss of appetite, constipation, excess gas, abnormal liver function tests, vomiting.
- Dry skin, skin disorder, loss of hair, skin ulcer, acne, skin thickening, skin nodule, increased sweating.
- Joint aches, bone pain, muscle aches.
- Chills, abdominal pain, allergic reaction, infection.

Uncommon (can occur in up to 1 in 100 patients treated):
- Blood disorders, eosinophilia, leukocytosis, lymphocytosis, purpura, elevated and decreased numbers of blood platelets.
- Overactive thyroid.
- Elevated bilirubin in the blood, impaired kidney function, gout, decreased HDL cholesterol. Agitation, difficulties with balance, depression, increased skin sensation on touching, abnormal nerve sensations, vertigo.
- Abnormal vision, blurred vision, inflammation of the eye lids, cataract, inflammation of the white part of the eye, lesion of the cornea of the eye, ear disorder, defect in field of vision. Swelling, bleeding, high blood pressure, fast heart rate, visible vein enlargement, dilation of blood vessels.
- Gastrointestinal disorder, liver failure, inflammation of the pancreas.
- Changes in hair, herpes simplex, nail disorder, pustular rash, serous drainage, skin discoloration.
- Muscle weakness.
- Proteins in urine, abnormal kidney function.
- Back pain, skin infection, fever, parasitic infection, abnormal laboratory test, disorder of mucous membrane, tumour.

Rare fatal side effects are acute inflammation of the pancreas, bleeding in the head, and liver failure.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bexarotene

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package to protect from light.

After the first opening of the bottle, use within 30 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bexarotene contains
- The active substance is bexarotene. Each capsule contains 75 mg of bexarotene.
- The other ingredients are:
  - o Capsule content: macrogol, polysorbate 20, povidone K90, butylated hydroxyanisole, purified water.
  - o Capsule shell: gelatin, glycerol, sorbitol, liquid, partially dehydrated, titanium dioxide (E171), purified water.

What Bexarotene looks like and contents of the pack
White to off-white oblong soft-gelatin capsule containing a white to off-white suspension. Bexarotene is available as soft capsules for oral use in a white plastic bottle containing 100 capsules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, Bad Vilbel, 61118, Germany

Other formats
To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

This leaflet was last revised in 04/2022

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