Celix Pharma

**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 75 mg Soft Capsules are and what they are used for

Bexarotene 75 mg Soft Capsules contain the active substance bexarotene, which belongs to a group of medicines known as retinoids, which are related to vitamin A.

Bexarotene is 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 75 mg Soft Capsules

### Do not take this medicine
- 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
- if you have uncontrolled lipid (blood fats) elevations (high blood cholesterol or high blood triglycerides)
- if you have a condition known as hypervitaminosis A
- if you have uncontrolled thyroid disease
- if you have insufficient liver function
- if you have an ongoing systemic infection

### Warnings and precautions
**Talk to your doctor or pharmacist before taking this medicine:**
- if you have a known allergy to retinoids (related to vitamin A)
- if you suffer from liver disease
- if you have high blood lipids (fats) or take medicines which may cause high blood lipids (fats)
- if you have uncontrolled diabetes mellitus (sugar diabetes)
- if you have had gall bladder or biliary tract disease
- if you 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 fat (lipid) levels may need to be checked before you start treatment with bexarotene and at weekly intervals afterwards, and then monthly while taking this medicine.
- Blood tests to check the function of your liver and thyroid gland and to check your red and white blood cell counts will be carried out before and during treatment with this medicine.
- Regular eye examinations may be needed if you experience visual difficulties while taking this medicine.
- Bexarotene can make you more sensitive to sunlight. 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 while taking this medicine.
- Do not donate blood while taking this medicine.

### 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 should not be used in children or adolescents.

### Other medicines and bexarotene
**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,** such as:
- ketoconazole and itraconazole (used for fungal infections)
- erythromycin, clarithromycin and rifampicin (used for bacterial infections)
- phenytoin and phenobarbital (used for seizures)
- gemfibrozil (used to reduce high levels of fats in the blood such as triglycerides and cholesterol)
- protease inhibitors (used for viral infections)
- tamoxifen (used for some forms of cancer)
- dexamethasone (used for inflammatory conditions)
- insulin, agents enhancing insulin secretion, or insulin-sensitisers (used for diabetes mellitus)
- vitamin A supplements (do not take more than 15,000 International Units of vitamin A supplements per day during treatment with bexarotene)

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
This medicine 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 treatment, do not drive or operate machinery.

### Bexarotene 75 mg Soft Capsules contain 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 this medicine.
- Butylated hydroxyanisole may cause irritation to the mucous membranes, therefore the capsules must be swallowed whole and not chewed.

## 3. How to take Bexarotene 75 mg Soft Capsules

Always take this medicine exactly as your doctor 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, as 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 decide 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.

**Tell your doctor or pharmacist if you get any of the following side effects or any side effects not listed.**

Very common (can occur in more than 1 in 10 patients treated):
- low white blood cell count
- lowering of thyroid hormones level
- increased 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
- increased liver enzymes, abnormal liver function tests, impaired kidney function, low protein in blood, weight gain
- difficulty sleeping (insomnia), dizziness, reduced skin sensation
- dry eyes, deafness, abnormal sensations of the eye including irritation and heaviness
- swelling of legs and arms
- feeling sick (nausea), diarrhoea, dry mouth, dry lips, loss of appetite, constipation, excess gas, being sick (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 such as raised levels of white blood cells; raised or reduced blood platelets (causing purple spots and patches on the skin and on mucus membranes such as inside the mouth)
- overactive thyroid
- raised bilirubin in the blood, impaired kidney function, gout, decreased HDL cholesterol
- agitation, difficulties with balance, depression, increased skin sensation on touching, abnormal nerve sensations, spinning sensation (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 (stomach or digestive problems), liver failure, inflammation of the pancreas
- changes in hair, herpes simplex (cold sores), nail disorder, pustular rash, weeping or oozing wounds, skin discoloration
- muscle weakness
- proteins in urine, abnormal kidney function
- back pain, skin infection, fever, parasitic infection, abnormal laboratory test, disorder of mucous membranes, 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 website 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 75 mg Soft Capsules

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. Keep the bottle tightly closed. 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 75 mg Soft Capsules contain
The active substance is bexarotene. Each capsule contains 75 mg bexarotene.
The other ingredients are macrogol, polysorbate, povidone, butylated hydroxyanisole and purified water.
The capsule shell consists of gelatin, glycerol, sorbitol liquid (partially dehydrated), titanium dioxide and purified water.

### What Bexarotene 75 mg Soft Capsules look like and contents of the pack
Bexarotene 75 mg Soft Capsules are white to off-white, oblong, soft capsules. They are packed in a white plastic bottle with a child-resistant cap, containing 100 capsules.

### Marketing Authorisation Holder
Celix Pharma Ltd
12 Constance Street
London, E16 2DQ
United Kingdom

### Manufacturer
GMP Manufacturing Ltd
Marfleet House
Valletta Street
Hull, HU9 5NP
United Kingdom

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