Package leaflet: Information for the user

Bicalutamide Actavis 50 mg film-coated tablets

bicalutamide

Read all of this leaflet carefully before you start using 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 Bicalutamide Actavis is and what it is used for

The growth of prostatic tumours is dependent on stimulation by male hormones (androgens). Bicalutamide Actavis contains the active substance bicalutamide, which prevents this stimulation. Bicalutamide Actavis is used in adult males in the treatment of advanced prostate cancer in combination with a type of medicine called LHRH analogues or surgical castration.

2. What you need to know before you take Bicalutamide Actavis

Do not use Bicalutamide Actavis
- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman or a child
- if you are already taking any medicine containing terfenadine, astemizole or cisapride.

Warnings and precautions
Talk to your doctor or pharmacist before using this medicine
- if you have any liver problems (your doctor may decide to do blood tests to check if your liver is working properly while you are taking this medicine),
- if you have diabetes (this medicine can affect the amount of glucose in the blood).

Please tell your doctor if you have any of the following:
Any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Bicalutamide Actavis.

Children and adolescents
Bicalutamide Actavis should not be used in children and adolescents.

Other medicines and Bicalutamide Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Bicalutamide Actavis may affect or be affected by the following medicines;
- ciclosporin, used in transplantation
- calcium channel blockers, to treat high blood pressure
- cimetidine, reduces the amount of acid in your stomach
- ketoconazole, antifungal medicine
- warfarin, anti-coagulant to prevent blood clots
- midazolam, used as sedative

See also section "Do not use Bicalutamide Actavis".

Bicalutamide Actavis might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs(e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Pregnancy and breast-feeding
Bicalutamide must not be used by women.

Driving and using machines
Bicalutamide Actavis is not likely to affect your ability to drive or use any machines. However, sleepiness may occur during treatment with Bicalutamide Actavis. Do not drive and use machines if you are affected.

Bicalutamide Actavis contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Bicalutamide Actavis

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

The recommended dose is 1 tablet once daily with or without food.

If you use more Bicalutamide Actavis than you should
If you have taken more medicine than you should, or for instance if a child has taken medicine by accident, please contact your doctor, the hospital or Poison Information Centre to get an opinion of the risk and advice on action to be taken.

If you forget to use Bicalutamide Actavis
If you forget a dose, skip the dose and take the next dose as usual. Do not take a double dose to make up for a forgotten tablet.

If you stop using Bicalutamide Actavis
Do not stop taking this medicine, even if you are feeling well, unless you are directly instructed to do so by your doctor.

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.

Contact your doctor or seek medical assistance immediately if you experience any of the following *uncommon* side effects (may affect up to 1 in 100 people).
- Severe shortness of breath, possibly coughing or fever. Signs of an inflammation of the lungs called interstitial pneumonia.
- The following allergic reactions (symptoms of angioedema): Swelling of the face, lips, tongue or throat, difficulty in swallowing, hives and trouble breathing.

Other side effects that may occur are:
Very common (may affect more than 1 in 10 people): Low levels of red blood cells (anaemia), dizziness, hot flushes, pain in the abdomen, constipation, nausea, blood in the urine, breast tenderness or enlarged breasts, feeling weak, swelling (oedema).

Common (may affect up to 1 in 10 people): Reduced appetite, reduced sex drive, depression, feeling sleepy, heart attack, heart failure, impaired digestion, wind (flatulence), changes in liver function, yellowing of the skin or eyes (jaundice), hair loss, increased hair growth on the body, dry skin, itching, rash, impotence, chest pain, weight gain.

Rare (may affect up to 1 in 1000 people): Liver failure, , sensitivity to sunlight.

Not known (frequency cannot be estimated from the available data):
Changes in ECG (QT prolongation)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bicalutamide Actavis

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

This medicine does not require any special storage conditions.

HDPE bottles only: Use within 6 months after opening.

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

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 Bicalutamide Actavis contains
- The active substance is bicalutamide 50 mg.
- The other ingredients are:
  Tablet core: lactose monohydrate, povidone, type A sodium starch glycolate, magnesium stearate.
  Tablet coating: macrogol 3350, polyvinyl alcohol, talc and titanium dioxide (E171).

What Bicalutamide Actavis looks like and contents of the pack
Appearance:
Bicalutamide Actavis 50 mg tablets are round, biconvex, white, 7 mm in diameter and imprinted with "B 50" on one side.

Package size:
Blister packs: 10, 14, 28, 30, 40, 50, 56, 84, 90, 98 and 100 tablets.
Bottles: 10, 14, 28, 30, 40, 50, 56, 84, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Actavis Group PTC ehf.,
Reykjavíkurvegi 76-78,
220 Hafnarfjörður,
Iceland

Manufacturer:
Actavis Group PTC ehf.,
Reykjavíkurvegur 78,
220 Hafnarfjörður,
Iceland

This medicinal product is authorised in the Member States of the EEA under the following names:

BG	BICUSAN
MT	Bicalutamide Actavis
CY; EL; SK	Brectasa
IS; NO; SE	Bicacta
AT	Bicacta 50 mg Filmtabletten
CZ	Bjorgeina 50 mg potahované tablety
EE	Bjorgeina
IE	Bicalutamide Actavis 50 mg Film-coated tablets
LV	Bjorgeina 50 mg apvalkotās tabletes
LT	Brectasa 50 mg plėvele dengtos tabletės
RO	Bicalutamida Actavis 50 mg comprimate filmate
UK	Bicalutamide 50 mg Film-coated tablets

This leaflet was last revised in December 2015