PACKAGE LEAFLET: INFORMATION FOR THE USER

BIKALUTAMID

50 mg film-coated tablets

BICALUTAMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Bicalutamide is and what it is used for
2. What you need to know before you take Bicalutamide
3. How to take Bicalutamide
4. Possible side effects
5. How to store Bicalutamide

1. WHAT BICALUTAMIDE IS AND WHAT IT IS USED FOR

Bicalutamide is one of a group of medicines known as the non-steroidal antiandrogens.

Bicalutamide is used for the treatment of advanced prostate carcinoma. It is taken together with a drug known as a luteinising hormone-releasing hormone (LHRH) analogue which reduces the levels of androgens (male sex hormones) within the body, or with accompanying surgical removal of the testicles.

The active substance bicalutamide blocks the undesired effect of the male sex hormones (androgens) and inhibits cell growth in the prostate in this way.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BICALUTAMIDE

Do not take Bicalutamide

- if you are allergic to bicalutamide or any of the other ingredients of this medicine
- if you are already take terfenadine or astemizole (for hay fever or allergy), or cisapride (for stomach disorders).

Bicalutamide should not be taken by women or must not be given to children and adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide .

- if your liver function is moderately or severely impaired. The drug should then only be taken after your doctor has carefully considered possible benefits and risks. If this is the case, your doctor will regularly perform tests of liver function (bilirubin, transaminases, alkaline phosphatase). If severe disturbances to liver function develop, treatment with Bicalutamide should be discontinued.
- if your renal function is severely impaired. The drug should then only be taken after your doctor has carefully considered possible benefits and risks.
- if you have diabetes and are already taking an "LHRH analogue". These include goserelin, buserelin, leuprorelin and triptorelin.
- if you suffer from heart disease. If this is the case, your doctor should regularly monitor your heart function.

Children and adolescents

Bicalutamide must not be given to children and adolescents.

Other medicines and Biculatamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Bicalutamide if you are already taking any of the following medicines:

- cisapride (for stomach disorders)
- terfenadine or astemizole (for hay fever or allergy).

If you take Bicalutamide together with one of the following medicines, the effect of bicalutamide as well as the other medicine may be influenced. Please speak to your doctor before taking any of these medicines together with Bicalutamide :

- warfarin or any similar medicine to prevent blood clots
  - ciclosporin (used to suppress your immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- calcium channel blockers (used to treat high blood pressure or some heart conditions)
- cimetidine (used to treat stomach ulcers)
- ketoconazole (used to treat fungal infections of the skin and nails).

Bicalutamide with food and drink

Bicalutamide can be taken before, during or after a meal, but also you can take this medicine without food. The film coated tablet should be swallowed with some water or another liquid.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Bicalutamide is contraindicated in females and must not be given to pregnant women or breast- feeding mothers.

Driving and using machines

Bicalutamide is unlikely to affect your ability to drive or to operate machinery. However, some people may occasionally feel drowsy when taking bicalutamide.
If you suffer from drowsiness you would be best advised not to carry out such tasks. However if you still drive a car or use machines you should exercise extra caution.

Bicalutamide 50 mg, film-coated tablets contain lactose

Bicalutamide 50 mg, film-coated tablets contain lactose monohydrate, which is a type of sugar.
If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor immediately.

3. HOW TO TAKE BICALUTAMIDE

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

The doctor prescribes an appropriate dosage for you personally. The recommended dose is one film-coated tablet once daily.

Try to take your tablet at the same time each day. Swallow the tablet whole with some liquid.

Use in children and adolescents
This medicine is not recommended for patients under the age of 18 years.

If you take more Bicalutamide than you should
If you have taken too many tablets contact your doctor or the nearest hospital as soon as possible. Take with you the remaining tablets or the pack so the doctor can identify what you have taken.

If you forget to take Bicalutamide
If you forget to take your daily dose, skip it when you remember it and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.
If you are worried, ask your doctor or pharmacist for advice.

If you stop taking Bicalutamide
Do not stop taking your film-coated tablets even if you feel healthy unless so advised 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.

Allergic reactions
These are uncommon (may affect up 1 in 100 users). The symptoms can include sudden onset of:

- rash, itching or hives of the skin
- swelling of the face, lips, tongue, throat or other parts of the body
- shortness of breath, wheezing or trouble breathing. If this happens to you, see a doctor straight away.

Also tell your doctor straight away if you notice any of the following:
Very common: may affect more than 1 in 10 users

- pain in your abdomen
- blood in your urine.

Common: may affect up to 1 in 10 users

- yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or in rare cases (may affect up to 1 in 1,000 users) liver failure.

Uncommon: may affect up to 1 in 100 users

- serious shortness of breath or shortness of breath which suddenly gets worse. This may be with a cough or high temperature (fever). These may be signs of an inflammation of the lungs called 'interstitial lung disease'.

Other possible side effects:

Very common: may affect more than 1 in 10 users

- dizziness

- constipation
- feeling sick (nausea)
- swelling and tenderness of your breasts
- hot flushes
- feeling weak
- swelling
- low levels of red blood cells (anaemia). This may make you feel tired and or look pale.

Common: may affect up to 1 in 10 users

- loss of appetite
- reduced sex drive
- depression
- feeling sleepy
- indigestion
- wind (flatulence)
- hair loss
- hair re-growth or growth of extra hair
- dry skin
- itching
- skin rash
- being unable to get an erection (impotence)
- weight gain
- chest pain
- reduced heart function
- heart attack.

Your doctor may do blood tests to check for any changes to your blood.
Do not be concerned by this list of possible side effects. You may not get any of them.

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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BICALUTAMIDE

Keep out of the sight and reach of children.
This medicine does not require any special storage conditions.

Do not use Bicalutamide after the expiry date which is stated on the blister and carton 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.

This leaflet was last revised in 06/2014.