

## Package leaflet: Information for the user

### Bicalutamide Avansor 50 mg, film-coated tablets bicalutamide

**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 Bicalutamide Avansor 50 mg is and what it is used for
2. What you need to know before you take Bicalutamide Avansor 50 mg
3. How to take Bicalutamide Avansor 50 mg
4. Possible side effects
5. How to store Bicalutamide Avansor 50 mg
6. Contents of the pack and other information

#### **1. What Bicalutamide Avansor 50 mg is and what it is used for**

Bicalutamide is an antiandrogen. This means it blocks the actions of male hormones (androgens) in the body. It also reduces the amount of male hormones made in the body.

Bicalutamide Avansor 50 mg is used in adult men to treat prostate cancer if you are also taking medicines called luteinising hormone-releasing hormone (LHRH)-analogues e.g. gonadorelin or have had or will soon have a surgical castration.

#### **2. What you need to know before you take Bicalutamide Avansor 50 mg**

##### **Do not take Bicalutamide Avansor 50 mg**

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6) if you are female
- if the tablets are to be given to a child
- if you are taking terfenadine or astemizole which are used to treat allergies or cisapride which is used to treat heartburn and acid reflux.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Bicalutamide Avansor 50 mg

- if you have a liver disease. Your doctor may decide to do blood tests to check your liver is working properly while you are taking this medicine.

- if you have diabetes. Treatment with bicalutamide in combination with luteinising hormone-releasing hormone (LHRH) analogues may alter your blood sugar level. Your dosage of insulin and/or oral antidiabetic medicines may need to be adjusted.
- if you have 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 Avansor 50 mg.

### **Other medicines and Bicalutamide Avansor 50 mg**

Other medicines may be affected by bicalutamide. They, in turn, may affect how well bicalutamide works. Bicalutamide can interact with:

- Cyclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow). This is because bicalutamide may increase the concentration of a substance called creatinine in your plasma and your doctor may take blood samples to monitor this.
- Midazolam (a medicine which is used to relieve anxiety before surgery or certain procedures or as an anaesthetic before and during surgery). You must tell your doctor or dentist you are taking bicalutamide if you need an operation or are very anxious in hospital.
- Terfenadine or astemizole which are used to treat allergies or cisapride which is used to treat heartburn and acid reflux (See section 2, Do not take Bicalutamide 50 mg).
- a type of medicine called a calcium channel blocker e.g. diltiazem or verapamil. These are used to treat heart problems, angina and high blood pressure.
- medicines to thin your blood e.g. warfarin.
- Cimetidine for acid reflux or stomach ulcers, or ketoconazole an antifungal medicine.
- Bicalutamide Avansor 50 mg 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).

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

### **Bicalutamide Avansor 50 mg with food and drink**

The tablets do not need to be taken with food but must be swallowed whole with a glass of water.

### **Pregnancy and breast-feeding**

This medicine must never be taken by women.

Ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

This medicine should not affect your ability to drive or use machines however some people may feel sleepy while taking this medicine. If you think your medicine is making you feel sleepy you must talk to your doctor or pharmacist before driving or using machines.

### **Bicalutamide Avansor 50 mg 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 take Bicalutamide Avansor 50 mg**

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

The recommended dose is one tablet, once a day. This must be swallowed whole with a glass of water. Try to take the medicinal product approximately at the same time each day.

You should start taking these tablets at least 3 days before starting treatment with LHRH analogues e.g. gonadorelin, or at the same time as undergoing surgical castration.

#### **If you take more Bicalutamide Avansor 50 mg than you should**

If you think that you may have taken more tablets than you should, 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. He or she may decide to monitor your body function until the effects of bicalutamide have worn off.

#### **If you forget to take Bicalutamide Avansor 50 mg**

If you think that you may have missed a dose of bicalutamide talk to your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose. Just take the normal dose at the usual time.

#### **If you stop taking Bicalutamide Avansor 50 mg**

Do not stop taking this medicine even if you are feeling well unless your doctor tells you to.

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.

If you get any of the following symptoms tell your doctor immediately or go to the casualty department at your nearest hospital. These are very serious side effects.

- Skin rash, itching, hives, peeling, blistering or crusting of the skin
- Swelling of the face or neck, lips, tongue or throat which may cause difficulty in breathing or swallowing
- Breathing problems with or without a cough and fever
- Yellow coloration of the skin or the eyes

Other possible side effects of the medicine are:

Very common side effects (may affect more than 1 in 10 people):

Low numbers of red blood cells (anaemia) • Breast soreness • Developments of breasts in males • Hot flushes • Dizziness • Pain in the stomach or pelvis • Constipation • Feeling sick • Presence of blood in the urine (haematuria) • Feeling weak • Swelling of the hands, feet, arms or legs (oedema)

Common side effects (may affect up to 1 in 10 people):

Lower sex drive • Depression • Sleepiness • Acid indigestion • Wind • Changes to liver function including yellowing of the skin and whites of the eyes (jaundice) • Hair loss • Increased hair growth • Dry skin • Rash • Itching of the skin • Difficulty in gaining an erection • Weight increase • Decreased appetite • Pain in the chest • Heart attack (fatal outcomes have been reported) • Heart problems which can cause shortness of breath or ankle swelling

Uncommon side effects (may affect up to 1 in 100 people):

Allergic reactions (hypersensitivity reactions). The symptoms of these may include: skin rash, itching, hives, peeling, blistering or crusting of the skin, swelling of the face or neck, lips, tongue or throat which may cause difficulty in breathing or swallowing • An inflammation of the lungs called interstitial lung disease (fatal outcomes have been reported). The symptoms of this may include severe breathlessness with a cough or fever

Rare side effects (may affect up to 1 in 1,000 people):

Liver failure (fatal outcomes have been reported)

Not known side effects (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 or pharmacist. 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](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Bicalutamide Avansor 50 mg**

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

Do not use this medicine after the expiry date stated on the blister and carton after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

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 Avansor 50 mg contains**

- The active substance is bicalutamide. Each tablet contains 50 mg bicalutamide.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, crospovidone, povidone K-29/32, sodium laurilsulfate

The ingredients in the tablet coating are: lactose monohydrate, hypromellose, macrogol 4000, titanium dioxide (E171).

**What Bicalutamide Avansor 50 mg looks like and contents of the pack**

The tablets are white, round, biconvex film-coated tablets, debossed with BCM50 on one side.

They are available in blisters of 5, 7, 10, 14, 20, 28, 30, 40, 50, 56, 80, 84, 90, 98, 100, 140, 200, and 280 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

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