

Package leaflet: Information for the user
BICALUTAMIDE 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 Tablets are and what they are used for
2. What you need to know before you take Bicalutamide Tablets
3. How to take Bicalutamide Tablets
4. Possible side effects
5. How to store Bicalutamide Tablets
6. Contents of the pack and other information

1. What Bicalutamide Tablets are and what they are used for

Bicalutamide Tablets contain a medicine called bicalutamide. This belongs to a group of medicines called “anti-androgens”.

- Bicalutamide Tablet is used to treat prostate cancer.
- It works by blocking the effects of male hormones such as testosterone.

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

Do not take Bicalutamide Tablets:

- If you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- If you are a woman
- If you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole).

Do not take Bicalutamide tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Bicalutamide tablets.

Bicalutamide tablets must not be given to children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide tablets.

- 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 tablets.
- if you are taking blood thinners or medicines to prevent blood clots.
- if you have problems with your liver.
- if you have diabetes and are already taking an ‘LHRH analogue’. These include goserelin, buserelin, leuprorelin and triptorelin.
- if you go into hospital, tell the medical staff that you are taking Bicalutamide Tablets.

- if you are taking Bicalutamide Tablets, you and/or your partner should use birth control while you are taking Bicalutamide Tablets and for 130 days after stopping Bicalutamide Tablets. Talk to your doctor if you have any questions about birth control.

Other medicines and Bicalutamide tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Bicalutamide tablets can affect the way other medicines work. Also some other medicines can affect the way Bicalutamide tablets works.

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

- Cisapride (used for some types of indigestion).
- Certain anti-histamine medicines (terfenadine or astemizole).

Bicalutamide tablets 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).

Also, tell your doctor or pharmacist if you are taking any of the following medicines e.g. warfarin. Blood thinners or medicines to prevent blood clots.:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants).
- Ciclosporin (to suppress your immune system)
- Cimetidine (for stomach problems)
- Ketoconazole (to treat infections caused by a fungus)
- Calcium channel blockers (to treat high blood pressure or some heart condition)

Pregnancy, breast-feeding and fertility

Bicalutamide Tablets must not be taken by women, including pregnant women or mothers who are breast-feeding their babies.

Bicalutamide Tablets may have an effect on male fertility which could be reversible.

Driving and using machines:

Bicalutamide Tablets are not likely to affect you being able to drive or use any tools or machines. However, if you feel sleepy take care with these activities.

Bicalutamide Tablets contains lactose

Bicalutamide Tablets contains lactose monohydrate, which is a type of sugar. 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 Tablets

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 for an adult is one tablet each day.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.
- Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

If you take more Bicalutamide Tablets than you should

If you take more Bicalutamide Tablets than prescribed by your doctor talk to a doctor or go to a hospital straight away.

If you forget to take Bicalutamide Tablets

- If you forget to take a dose, skip the missed dose and take the next dose as usual.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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

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 to 1 in 100 people)**.

The symptoms can include sudden onset of:

- Rash, itching or hives on 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 people):

- Pain in your abdomen.
- Blood in your urine.

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

- 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 people) liver failure.

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

- 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'.

Not known (frequency cannot be estimated from the available data):

- Changes in ECG (QT prolongation).

Other possible side effects:

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

- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.
- Dizziness.
- Swelling and tenderness of your breasts.
- Feeling weak.
- Hot flushes.
- Constipation.
- Feeling sick (nausea).
- Swelling.

Common (may affect up to 1 in 10 people)

- Loss of appetite.
- Indigestion.
- Wind (flatulence).
- Weight gain.
- Itching.
- Dry skin.
- Skin rash.
- Being unable to get an erection (impotence).

- Reduced sex drive.
- Depression.
- Feeling sleepy.
- Hair loss.
- Hair re-growth or growth of extra hair.
- Chest pain.
- Reduced heart function.
- Heart attack.

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

- Increased skin sensitivity to sunlight.

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. 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 Tablets

- This medicinal product does not require any special storage conditions
- Keep out of the sight and reach of children.
- Do not use Bicalutamide Tablets after the expiry date which is stated on the Carton and blister (EXP). The expiry date refers to the last day of that month e.g. mm/yyyy.
- 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 Tablets contains:

The active substance is Bicalutamide.

Each film-coated tablet contains 50mg of bicalutamide.

Excipients:

Tablet core:

lactose monohydrate

sodium starch glycolate (Type A)

povidone K-30

magnesium stearate.

Film coat:

Hypromellose E5

titanium dioxide E171

Macrogol 400.

What Bicalutamide Tablets looks like and content of the pack:

Bicalutamide 50 mg film-coated Tablet is a white to off white, round biconvex, film-coated tablets debossed 'B 50' on one side and plain on other side.

Bicalutamide 50 mg film-coated Tablets are packed in blisters in pack of 14, 20, 28, 30, 60, 84, 90, 98 or 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Accord Healthcare Ireland Limited, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer

Accord Healthcare Limited,
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