

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”.

These drugs block a number of the effects of the male sex hormone androgen in the body. One of the effects of androgen is that it stimulates tumour growth. Anti-androgens inhibit tumour growth.

This medicine is used to inhibit growth of a tumour on the prostate and to improve quality of life (palliative treatment).

This medicine is only prescribed for men with inoperable metastatic prostate cancer in whom the testes have been fully or partially removed or who are using an LHRH agonist (a type of medicine that inhibits formation of testosterone by the body).

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 (including women who are pregnant or breast-feeding)
- 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. Your doctor will want to check your liver function regularly.
- if you have diabetes and are already taking an 'LHRH analogue'. These include goserelin, busserelin, leuprorelin and triptorelin. The active substance in this medicine (bicalutamide) can have a negative effect on the level of sugar in your blood. Your doctor will therefore want to check your blood sugar levels regularly.
- 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 or pharmacist 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:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants) e.g. warfarin, coumarin derivatives.
- 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)

Bicalutamide Tablets with food and drink

You can take this medicine with or without food. This does not affect the amount of the medicine entering the bloodstream.

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 contain lactose

Lactose 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.

Bicalutamide Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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 is one 50 mg tablet daily. This applies to all adult males.
- 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, talk to a doctor or go to a hospital straight away. Take the pack with you.

If you forget to take Bicalutamide Tablets

- If you realise you have forgotten to take this medicine at the usual time, you can still take it later the same day.
- However, if you only remember on the following day that you have forgotten to take this medicine, 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 stop taking Bicalutamide Tablets

Take this medicine as your doctor or pharmacist has told you. If you are thinking of stopping using this medicine, talk to your doctor first. This is because suddenly stopping or interrupting the use of this medicine can have adverse effects.

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. The following side effects can occur when using this medicine.

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

- Anaemia.
- Dizziness.
- Hot flushes.
- Nausea.
- Constipation.
- Abdominal pain.
- Traces of blood in the urine (haematuria).
- Development of breasts (gynaecomastia).
- Sensitivity of the nipples and/or the surrounding area.
- Feeling weak (asthenia).
- Fluid accumulation (oedema).

Common (may affect between 1 and 10 out of 100 users)

- Lack of appetite.
- (Severe) dejection (depression).
- Low sex drive (reduced libido).
- Drowsiness.
- Insufficient pumping power of the heart (heart failure).
- Heart attack; fatalities have been reported.
- Disturbed digestion. This can manifest as a feeling of fullness in the upper abdomen, pain in the stomach area, belching, nausea, vomiting and heartburn (dyspepsia).
- Wind (flatulence).
- Liver function changes (increase in certain liver enzymes (transaminases), jaundice).
- Liver and biliary disorders.
- Itching (pruritus).
- Dry skin.
- Hair loss (alopecia).
- Skin rash.
- Excessive hair (hirsutism).
- Erectile dysfunction (impotence).
- Chest pain.
- Weight gain.

Uncommon (may affect between 1 and 10 out of 1,000 users)

- Hypersensitivity reactions such as sudden fluid accumulation in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (angioedema) or skin rash with severe itching and formation of hives (urticaria).
- Interstitial lung disease; cases with a fatal outcome have been reported.

Rare (may affect between 1 and 10 out of 10,000 users)

- Reduced function of the liver (liver failure); fatalities have been reported.
Increased sensitivity of the skin to sunlight.

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

- Changes on ECG (prolongation of the QT interval).

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

Website: www.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 this medicine 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 coating:

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 Polska Sp.z o.o.,
ul. Lutomska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Single Member,
64th KM Athens Lamia National Highway,
Schimatari, Viotia, 32009, Greece

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

Name of Member State	Name of medicinal product
Estonia	Bicalutamide Accord 50mg õhukese polümeerikattega tabletid
Ireland	Bicalutamide 50mg Film-coated Tablets
Italy	Bicalutamide AHCL 50 mg Compresse rivestite con film
Latvia	Bicalutamide Accord 50 mg apvalkotās tabletes
Portugal	Bicalutamida Accord 50 mg comprimidos revestidos por película
Spain	Bicalutamida Accord 50 mg comprimidos recubiertos con película EFG
The Netherlands	Bicalutamide Accord 50 mg Filmomhulde Tabletten
United Kingdom	Bicalutamide 50mg Film-coated Tablets

Bulgaria	Bicalutamide Accord 50mg Film-coated Tablets
Cyprus	Bicalutamide Accord 50mg Film-coated Tablets
Lithuania	Bicalutamide Accord 50 mg plėvele dengtos tabletės
Poland	Bicalutamide Accord
Romania	Bicalutamida Accord 50 mg, comprimate filmate

The leaflet was last revised in 02/2024.