

Package leaflet: information for the user

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

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

Bicalutamide belongs to a group of medicines called anti-androgens. Anti-androgens act against the effects of androgens (male sex hormones).

Bicalutamide is used in adult men to treat advanced prostate cancer. It is taken after surgical removal of the testicles or together with another type of hormone treatment known as luteinising hormone-releasing hormone (LHRH) analogue. These treatments block the undesired effects of the male sex hormones and this slows down the growth of the cancer cells.

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

Do not take Bicalutamide 50 mg

- If you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).
- If you are taking anti-histamines called terfenadine or astemizole (used to treat rash and hay fever) or cisapride (used for some types of indigestion) (see “Other medicines and Bicalutamide 50 mg”).
- If you are a woman

Bicalutamide must not be given to children or adolescents.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide 50 mg

- Tell your doctor if you have any liver problems, he will decide if you should take this medicine. If you do take it your doctor will give you regular blood tests to check your liver function. If your liver is severely affected by taking Bicalutamide treatment will be stopped.

- Tell your doctor if you have any severe kidney problems, he will decide if you should take this medicine.
- If you have diabetes. Treatment with bicalutamide in combination with an LHRH analogue may alter your blood sugar level. Your dosage of insulin and/or oral antidiabetic medicine may need to be adjusted
- If you go into hospital let the medical staff know you are taking bicalutamide.

If any of these apply to you and you have not already discussed these with your doctor, you should talk to your doctor or pharmacist before taking these tablets.

Other medicines and Bicalutamide 50 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines
It is especially important to mention:

- Antihistamines called terfenadine and astemizole (for hay fever or allergies) (see also “Do not take” above)
- Cisapride (for some types of indigestion) (see also “Do not take” above)
- Oral anti-coagulants such as warfarin (to prevent blood clots).
- Ciclosporin (used to suppress your 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.
- Cimetidine (to treat stomach ulcers)
- Midazolam (used as a tranquiliser). You must tell your doctor or dentist you are taking bicalutamide if you need an operation or are very anxious in hospital.
- Ketoconazole (to treat fungal infections of the skin and nails)
- Calcium channel blockers such as nifedipine or verapamil (to treat high blood pressure or some heart conditions).

Bicalutamide 50 mg with food and drink

The Bicalutamide 50 mg tablet may be taken with or without food.

Pregnancy and breast-feeding and fertility

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

Women must not take Bicalutamide tablets.

Bicalutamide may induce a period of sub-fertility or infertility in men.

Driving and using machines

Your medicine is unlikely to affect your ability to drive a vehicle or operate machinery. However some people may occasionally feel dizzy or drowsy when taking bicalutamide. If you do feel dizzy or drowsy, you should exercise extra caution when carrying out such tasks.

Bicalutamide 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 50 mg

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

Unless your doctor tells you otherwise, the usual dose is one tablet daily. It is important that you take your medicine at the same time each day, usually in the morning or in the evening.

Swallow the tablet whole with a drink of water.

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.

Use in children and adolescents

Children and teenagers under 18 years of age must not take Bicalutamide.

If you take more Bicalutamide 50 mg than you should

If you take an overdose of tablets or a child swallows tablet(s) accidentally, consult your doctor or the nearest casualty department immediately. Take this leaflet or some tablets with you so that the doctor will know what you have taken.

If you forget to take Bicalutamide 50 mg

If you forget to take your Bicalutamide tablet, skip the forgotten dose and take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Bicalutamide 50 mg

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

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 suffers from them.

If you experience any of the following stop taking Bicalutamide 50 mg and seek medical help immediately:

- Serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. You may have an inflammation of the lungs called interstitial lung disease
- Severe itching of the skin (with raised lumps), swelling of the, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing. You may have a serious allergic reaction to bicalutamide.

All of these are serious side effects and are uncommon (affect up to 1 in 100 users).

- Blood in the urine (haematuria)
- Abdominal pain

These side effects are very common (affect more than 1 in 10 people).

- Yellowing of your skin and whites of the eyes (jaundice). These may be signs of liver problems or in rare cases (less than 1 in 1,000 people) liver failure.

This side effect is common (affects up to 1 in 10 people)

The following side effects may also occur:

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

- Swelling and tenderness of your breasts
- Hot flushes
- Dizziness
- Constipation
- Feeling sick (nausea)

- Feeling weak
- Swelling of the hands, feet, arms or legs (oedema)
- Low numbers of red blood cells (anaemia)

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

- Lower sex drive
- Depression
- Sleepiness
- Acid indigestion
- Wind
- Liver toxicity, elevated levels of liver enzymes, yellowing of the skin and whites of the eyes (jaundice)
- Hair loss or hair growth
- Excessive hairiness
- Dry skin
- Rash
- Itching of the skin
- Heart attack, reduced heart function
- Difficulty in gaining an erection (impotence)
- Weight gain
- Loss of appetite
- Pain in the chest

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

- Liver failure (with possible fatal outcome)

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 the:

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6767836

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

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

5. How to store Bicalutamide 50 mg

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

This medicinal product does not require any special storage conditions.

Do not use this medicine 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 medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Bicalutamide 50 mg contains

The active substance is bicalutamide. Each film-coated tablet contains 50 mg of bicalutamide.

The other ingredients are:

- Tablet core: Lactose monohydrate, Sodium starch glycolate type A, Povidone, Crospovidone type B, Magnesium stearate
- Film-coating: Hypromellose, Macrogol 300, Titanium dioxide (E-171).

What Bicalutamide 50 mg tablets look like and contents of the pack

Bicalutamide 50 mg is a white, round, biconvex, film-coated tablet. The tablets are packed in blister packs in a carton box, containing 28, 30 or 90 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Farmaprojects SAU
Santa Eulàlia 240-242
08902 L'Hospitalet de Llobregat
Barcelona
Spain

Manufacturers:

Medicamentos Internacionales SA, MEDINSA
Solana 26, 28850 Torrejón de Ardoz, Madrid (Spain)

Rafarm, SA
12th Kapodistriou & Korinthou str. - n. Psyhico 15451 – Athens

Excella GmbH
Nürnberg Strasse 12, 90537 Feucht (Germany)

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

Ireland: Bicalutamide Farmaprojects 50 mg film-coated tablets
Germany: Bicalutamid bioeq pharma 50 mg Filmtabletten
Spain: Bicalutamida Apotex 50 mg comprimidos recubiertos con película EFG
Italy: Praxis 50 mg compresse rivestite con film
EL: Bicalutamide/Specifar

This leaflet was last revised in March 2014