

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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bicalutamide 50 mg is and what it is used for
2. Before you take Bicalutamide 50 mg
3. How to take Bicalutamide 50 mg
4. Possible side effects
5. How to store Bicalutamide 50 mg
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1. WHAT BICALUTAMIDE 50 mg IS AND WHAT IT IS USED FOR

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. Bicalutamide is one of a group of medicines known as the non-steroidal antiandrogens. 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. BEFORE YOU TAKE BICALUTAMIDE 50 mg

Do not take Bicalutamide 50 mg

- if you are allergic (hypersensitive) to bicalutamide or any of the other ingredients of Bicalutamide
 - if you take terfenadine (for hay fever or allergy), 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.

Take special care with Bicalutamide 50 mg 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 functions is severely impaired.** The drug should then only be taken after your doctor has carefully considered possible benefits and risks.

- **if you suffer from heart disease.** If this is the case, your doctor should regularly monitor your heart function.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take Bicalutamide 50 mg 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 50 mg.

- warfarin or any similar medicine to prevent blood clots,
- terfenadine or astemizole (for hay fever or allergy),
- cisapride (for stomach disorders),
- cyclosporin (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).

Taking Bicalutamide 50 mg with food and drink

Bicalutamide 50 mg can be taken before, during or after a meal, but also you can take them without food. The film coated tablet should be swallowed with some water or another liquid.

Pregnancy and breast-feeding

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

Bicalutamide 50 mg is contra-indicated in females and must not be given to pregnant or breast-feeding mothers.

Driving and using machines

Bicalutamide 50 mg is unlikely to affect your ability to drive or to operate machinery.

However, some people may occasionally feel drowsy when taking Bicalutamide 50 mg. If this happens to you, you should exercise caution when carrying out such tasks. If you suffer from dizziness or 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.

Important information about some of the ingredients of Bicalutamide 50 mg

Bicalutamide 50 mg contains lactose. 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 50 mg

Always use Bicalutamide 50 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The doctor prescribes an appropriate dosage for you personally. The usual dose is one film-coated tablet once daily. Read the instruction label on the package. Tablets are swallowed whole with some liquid. Try to take the medicinal product approximately at the same time each day.

Children and adolescents: This medicine is not recommended for patients under the age of 18 years.

If you take more Bicalutamide 50 mg 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.

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If you forget to take Bicalutamide 50 mg

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 50 mg

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bicalutamide 50 mg can cause side effects, although not everybody gets them.

You should contact your doctor straight away if you notice any of the following serious side effects:

Very rare side effects (affecting less than 1 in 10,000 people):

- severe disturbances in liver function (liver failure)
- chest pain and heart failure (which may be associated with breathlessness, especially on exertion, a fast heart beat, swelling in the limbs and mottling of the skin), irregular heart beat, abnormal ECG heart tracing.
- reduction in blood platelets which increases risk of bleeding or bruising.

Uncommon serious side effects (affecting less than 1 in 100 people):

- serious allergic reaction which causes swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing or breathing or severe itching of the skin with raised lumps.
- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. Some patients taking Bicalutamide get an inflammation of the lungs called interstitial lung disease.

Tell your doctor if any of the following side effects bother you:

Side effects that are very common (estimated frequency is more than 1 person out of 10):

- tender or enlarged breast tissue.
- reduced sexual desire, erection problems, impotence.
- hot flushes.

Side effects that are common (estimated frequency is less than 1 person out of 10 but more than 1 out of 100):

- diarrhoea
- sleeplessness
- having frequent loose or liquid bowel movements
- disturbances in the function of the liver (elevated levels of liver enzymes, yellowing of the skin or whites of the eyes [jaundice] due to interruption in the excretion of bile [choestasis]), enlarged liver.
- chills, general pain and swelling
- sweating
- constipation
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- dizziness
- weight gain
- itching
- feeling weak
- nausea
- pelvic pain
- rash
- excessive hair growth
- diabetes mellitus

Side effects that are uncommon (estimated frequency is less than 1 person out of 100 but more than 1 out of 1000):

- indigestion
- depression
- hair loss
- weight loss
- severe allergic reactions
- shortness of breath (dyspnoea)
- abdominal pain
- drowsiness
- needing to urinate during the night
- blood in urine
- inflammation of the lungs called interstitial lung disease
- chest pain
- back pain
- neck pain
- headache
- dry mouth
- flatulence
- loss of appetite (anorexia)
- hyperglycaemia (high blood sugar levels)
- severe itching of the skin (with raised lumps) or swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing

Side effects that are rare (estimated frequency is less than 1 person out of 1000 but more than 1 out of 10,000)

- dry skin
- vomiting

Side effects that are very rare (estimated frequency is less than 1 in 10,000 people):

- severe disturbances in liver function (liver failure)
- chest pain and heart failure (which may be associated with breathlessness, especially on exertion, a fast heart beat, swelling in the limbs and mottling of the skin), irregular heart beat, abnormal ECG heart tracing.
- reduction in blood platelets which increases risk of bleeding or bruising.

Occasionally, Bicalutamide 50 mg may be associated with changes in your blood, which may require your doctor to do certain blood tests.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BICALUTAMIDE 50 mg

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

Do not use Bicalutamide 50 mg after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Bicalutamide 50 mg contains

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

Tablet core:

The other ingredients are: Lactose monohydrate, Povidone K- 25, Sodium starch glycolate (Type A), Magnesium Stearate.

Film coating

Opadry OY-S-9622 which contains Hypromellose 5cp (E464), Titanium dioxide (E171) and Propylene Glycol.

What Bicalutamide 50 mg looks like and contents of the pack

Bicalutamide 50 mg is supplied as white, round, biconvex film-coated tablets. The tablets are packed in blister packs containing 28 & 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viogen Pharmaceuticals Ltd
309 El. Venizelou Str.,
176 74 Kallithea
Athens, Greece

Manufacturer

Genepfarm S.A
18th klm Marathonos Avenue
153 51 Pallini Attikis
Greece

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

UK: Bicalutamide 50 mg Film Coated Tablets

EL: PROBICON VIOGEN

This leaflet was last approved on 21 April 2010