

PACKAGE LEAFLET: INFORMATION FOR THE USER



Bicalutamide

150 mg Film-coated Tablets

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 150 mg is and what it is used for
2. What you need to know before you take Bicalutamide 150 mg
3. How to take Bicalutamide 150 mg
4. Possible side effects
5. How to store Bicalutamide 150 mg
6. Contents of the pack and other information

1. What Bicalutamide 150 mg is and what it is used for

Bicalutamide 150 mg Film-coated Tablets contain a medicine called bicalutamide. This belongs to a group of medicines called ‘anti-androgens’.

- Bicalutamide 150 mg 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 150 mg

Do not take Bicalutamide 150 mg

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

Bicalutamide 150 mg must not be given to children.

Do not take Bicalutamide 150 mg if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Bicalutamide 150 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide 150 mg:

- if you have problems with your liver. Your doctor may do blood tests before and during your treatment with Bicalutamide 150 mg,
- 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 50 mg,
- if you are taking Bicalutamide 150 mg, you and/or your partner should use birth control while you are taking Bicalutamide 150 mg and for 130 days after stopping Bicalutamide 150 mg. Talk to your doctor if you have any questions about birth control,
- If you go into hospital, tell the medical staff that you are taking Bicalutamide 150 mg.

Children and adolescents

Bicalutamide 150 mg must not be given to children or adolescents.

Tests and checks

Your doctor may do blood tests to check for any changes to your blood.

Other medicines and Bicalutamide 150 mg

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 150 mg can affect the way other medicines work. Also some other medicines can affect the way Bicalutamide 150 mg works.

Do not take Bicalutamide 150 mg 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 150 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)].

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). Blood thinners or medicines to prevent blood clots. Your doctor may do blood tests before and during your treatment with Bicalutamide 150 mg.
- Ciclosporin (to suppress your immune system).
- Calcium channel blockers (to treat high blood pressure or some heart conditions).
- Cimetidine (for stomach problems).
- Ketoconazole (to treat infections caused by a fungus).

Pregnancy and breast-feeding

Bicalutamide 150 mg must not be given to a woman.

Driving and using machines

Bicalutamide 150 mg is not likely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel sleepy while taking Bicalutamide 150 mg. If this happens to you, ask your doctor or pharmacist for advice.

Bicalutamide 150 mg Film-coated Tablets contain lactose

Bicalutamide 150 mg Film-coated Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sunlight or Ultraviolet (UV) light

Avoid direct exposure to excessive sunlight or UV-light while you are taking Bicalutamide 150 mg.

Important information about Bicalutamide 150 mg

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

3. How to take Bicalutamide 150 mg

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



pharmacopoeia
reading direction

The recommended dose 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.

Use in Children and adolescents

Bicalutamide 150 mg must not be given to children.

If you take more Bicalutamide 150 mg than you should

If you take more Bicalutamide 150 mg than prescribed by your doctor, talk to a doctor or go to a hospital straight away. If possible, take your medicine or the box with you to show the doctor what you have taken.

If you forget to take Bicalutamide 150 mg

If you forget to take a dose, skip the missed dose and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Bicalutamide 150 mg

Do not stop taking this medicine, even if you feel 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.

Tell your doctor straight away if you notice any of the following side effects- you may need urgent medical treatment:

Allergic reactions (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.

Also tell your doctor straight away if you notice any of the following:

Common (may affect more than 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.
- Pain in your abdomen.
- Blood in your urine.

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)

- Skin rash.
- Swelling and tenderness of your breasts.
- Feeling weak.

Common (may affect up to 1 in 10 people)

- Hot flushes.
- Feeling sick (nausea).
- Itching.
- Dry skin.
- Problems getting an erection (erectile dysfunction).
- Putting on weight.
- Reduced sex drive and reduced fertility.
- Hair loss.
- Hair re-growth or growth of extra hair.
- Low levels of red blood cells (anaemia).

This may make you feel tired or look pale.

- Loss of appetite.
- Depression.
- Feeling sleepy.
- Indigestion.
- Dizziness.
- Constipation.
- Wind (flatulence).
- Chest pain.
- Swelling.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bicalutamide 150 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 carton after 'EXP'. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Bicalutamide 150 mg contains

- The active substance is bicalutamide. Each film-coated tablet contains 150mg bicalutamide.
- The other ingredients are:
Tablet core: lactose monohydrate, povidone K- 25, sodium starch glycolate-type A and magnesium stearate.
Film coating: opadry OY-S-9622 which contains hypromellose (E464), titanium dioxide (E171) and propylene glycol.

What Bicalutamide 150 mg looks like and contents of the pack

Bicalutamide 150 mg Film-coated Tablets are supplied as white, round, biconvex film-coated tablets with a score line on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal parts.

The film-coated tablets are packed in blister packs containing 10, 14, 20, 28, 30, 40, 56, 60, 100 and 150 tablets contained in a carton.

Marketing Authorisation Holder

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester
LE19 1WP
UK

Manufacturer

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

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