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Package leaflet: Information for the user

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

1. What Bicalutamide is and what it is used for

Bicalutamide belongs to a group of medicines called anti-androgens.

It works by blocking the effects of male hormones such as testosterone and inhibits cell growth in the prostate.

Bicalutamide 150 mg can be used alone but can also be given as part of a combination treatment to patients that have had their prostate removed. Additionally in combination with radiation therapy for the treatment of prostate cancer, whereby the cancer has spread from the capsule of the prostate gland to the close surrounding tissue. These patients are at high risk for the cancer to spread.

2. What you need to know before you take Bicalutamide

Do not take Bicalutamide

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6)
- if you are already taking terfenadine or astemizole (to treat allergies), or cisapride (to treat stomach disorders).

Bicalutamide should not be given to women, children and adolescents (see sections “How to take Bicalutamide” and “Pregnancy, breast-feeding and fertility”).

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

Warning and precautions

Talk to your doctor or pharmacist before taking Bicalutamide.

In particular tell your doctor if you have any of the following conditions:

- if you have heart rhythm problems, or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Bicalutamide.
- if you have moderate or severe liver problems, your doctor will regularly prescribe tests of liver function.

Your doctor will inform you about the need for effective contraception, you and your partner should follow adequate contraception during and for 130 days after Bicalutamide therapy (see “Pregnancy, breast-feeding and fertility”).

Bicalutamide may cause a period of subfertility or infertility as a result of morphological changes in male reproductive cells (sperm), see section “Pregnancy, breast-feeding and fertility”.

Talk to your doctor if your condition worsens and PSA (a blood test used to evaluate prostate functionality), is increased because, treatment with Bicalutamide 150 mg might be discontinued.

You should take Bicalutamide 150 mg as prescribed by your doctor and do not stop treatment unless your doctor tells you to.

In the event of hospitalization, inform the medical staff that you are being treated with Bicalutamide 150 mg.

Other medicines and Biculatamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- cisapride (used to treat stomach disorders)
- terfenadine or astemizole (used to treat allergies).

Bicalutamide might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, disopyramide, amiodarone, dofetilide, ibutilide and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs, e.g. methadone (used to treat severe pain and to treat withdrawal symptoms in case of addiction), moxifloxacin (an antibiotic used to treat infections caused by bacteria), antipsychotics (used for mental disorders).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- oral anti-coagulants (medicines taken by mouth to prevent blood clots e.g.warfarin). Your doctor may do blood tests before and during your treatment with Biculatamide
- ciclosporin (used to prevent and treat rejection of a transplanted organ or bone marrow and to treat autoimmune diseases)
- calcium channel blockers (used to treat high blood pressure or some heart conditions)
- cimetidine (used to treat stomach ulcers)
- ketoconazole (used to treat infections caused by a fungus).

Pregnancy, 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.

Pregnancy and breast-feeding

Bicalutamide must not be taken by women (see section “Do not take Bicalutamide”).

Fertility

Bicalutamide may have an effect on male fertility which may be reversible (see section “Warning and precaution”).

Contraception in women and men

You and your partner must use effective contraception measures when taking Bicalutamide and for 130 days after stopping treatment (see section “Warning and precaution”).

Driving and using machines

Since somnolence may occur Bicalutamide may impair the ability to drive and use machines.

Sunlight or Ultraviolet (UV) light

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

Bicalutamide 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 immediately.

Bicalutamide contains 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

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 tablet once daily.

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 must not be given to children and adolescent (see section “Do not take Bicalutamide”).

If you take more Bicalutamide than you should

If you have taken more Bicalutamide than prescribed by your doctor, talk to a doctor or go to a hospital straight away.

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Take with you the remaining tablets or the pack so the doctor can identify what you have taken.

If you forget to take Bicalutamide

If you forget to take a dose, skip the missed dose and take the next dose as usual time. 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 for advice.

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

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.

Common (may affect up to 1 in 10 people)

- jaundice (yellowing of the skin or whites of your eyes), hypertransaminasemia (unusually high levels of liver enzymes in blood that may be an indicator of liver dysfunction. These may be signs of liver problems or, in rare cases (may affect up to 1 in 1,000 people) liver failure, fatal outcomes have been reported.
- Abdominal pain
- haematuria (blood in 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 fever (high temperature). These may be signs of an inflammation of the lungs called 'interstitial lung disease', fatal outcomes have been reported.

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

- QT prolongation (a heart rhythm disorder), see "Warning and precaution" and "Other medicines and Bicalutamide).

Other possible side effects:

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

- swelling and tenderness of your breast tissue
- asthenia (feeling weak).

Common (may affect up to 1 in 10 people)

- hot flushes
- nausea (feeling sick)
- dry skin
- erectile dysfunction (problems getting an erection)
- weight increased
- decreased libido (reduced sexual desire)
- alopecia (hair loss)
- hirsuitism (hair on parts of the body where normally is absent or minimal)/hair re-growth
- anaemia(reduction of red cells number or reduction of the haemoglobin concentration, a protein in red blood cells that carries oxygen). This may make you feel tired or look pale.
- decreased appetite
- depression
- somnolence (feeling sleepy)
- dyspepsia (difficult digestion)
- dizziness(sensation of falling or movement)
- constipation
- flatulence(excessive gas production by the gut)
- chest pain
- oedema (accumulation of fluid in a particular part of the body).

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

- photosensitivity reaction (increased skin sensitivity to sunlight).

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

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

This medicine 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 any medicine 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 contains

- The active substance is bicalutamide. Each film-coated tablet contains 150 mg biclutamide.
- The other ingredients are:

  Tablet core: lactose monohydrate, magnesium stearate, sodium starch glycolate Type A, povidone.

  Film coating: opadry II white (33F28627) containing hypromellose 6CP (E464), titanium dioxide (E 171), macrogol 3000.

What Bicalutamide looks like and contents of the pack

Bicalutamide 150 mg film-coated tablet is a white to off white, circular, biconvex, film-coated tablet debossed with '507' on one side and plain on the other side, and contains 150 mg bicalutamide.

Bicalutamide 150 mg film-coated tablets are available in packs of 28, 30 and 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sun Pharmaceutical Industries Europe B.V.

Polarisavenue 87

2132 JH Hoofddorp

The Netherlands

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom(Northern Ireland) under the following names:

Italy	Bicalutamide SUN 150 mg compresse rivestite con film
United Kingdom **(Northern Ireland)**	Bicalutamide 150 mg film-coated tablets

This leaflet was last revised in 02/2025.

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