

BICALUTAMIDE TEVA 50 mg FILM-COATED TABLETS

Bicalutamide

PATIENT LEAFLET: INFORMATION FOR THE USER

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

1 What Bicalutamide Teva is and what it is used for

Bicalutamide contains a medicine called bicalutamide. This belongs to a group of medicines called 'anti-androgens'.

- Bicalutamide Teva 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 Teva

Do not take Bicalutamide Teva

- 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.

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.

Bicalutamide must not be given to children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bicalutamide Teva:

- 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 Teva.
- if you are taking blood thinners or medicines to prevent blood clots.
- if you have problems with your liver.
- if you have diabetes and are already taking an 'LHRH analogue'. These include goserelin, busserelin, leuporelin and triptorelin.
- if you go into hospital, tell the medical staff that you are taking Bicalutamide Teva.
- if you are taking Bicalutamide Teva, you and/or your partner should use birth control while you are taking Bicalutamide Teva and for 130 days after stopping Bicalutamide Teva.

Talk to your doctor if you have questions about birth control.

Other medicines and Bicalutamide Teva

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

Do not take Bicalutamide Teva 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 Teva 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 illness.

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. Blood thinners or medicines to prevent blood clots.
- 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, breast-feeding and fertility

Bicalutamide must not be taken by women, including pregnant women or mothers who are breast-feeding their babies.

Bicalutamide may have an effect on male fertility which could be reversible.

Driving and using machines

Bicalutamide Teva is 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 Teva 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.

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 Teva

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 for an adult 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.
- Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

If you take more Bicalutamide Teva than you should

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

If you forget to take Bicalutamide Teva

- If you forget to take a dose, 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 Teva

Do not stop taking the medicine even if you feel absolutely healthy, 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.

Contact your doctor or seek medical help immediately if you experience any of the following:

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. If this happens to you, **see a doctor straight away.**

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

Very common: may affect more than 1 in 10 people

- Pain in your abdomen.
- Blood in your urine.

Common: may affect up to 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.

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

- Dizziness.
- Constipation.
- Feeling sick (nausea).
- Swelling and tenderness of your breasts.
- Hot flushes.
- Feeling weak.
- Swelling.
- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.

Common: may affect up to 1 in 10 people

- Loss of appetite.
- Reduced sex drive.
- Depression.
- Feeling sleepy.
- Indigestion.
- Wind (flatulence).
- Hair loss.
- Hair re-growth or growth of extra hair.
- Dry skin.
- Itching.
- Skin rash.
- Being unable to get an erection (impotence).
- Weight gain.
- Chest pain.
- Reduced heart function.
- Heart attack.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie;

E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Bicalutamide Teva

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

Store in the original package.

Do not use this medicine after the expiry date which is stated on the blister and outer packaging. 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 protect the environment.

6 Contents of the pack and other information

What Bicalutamide Teva contains

- The active substance is bicalutamide. Each film-coated tablet contains 50 mg bicalutamide.
- The other ingredients are:
Core: Microcrystalline cellulose, povidone, croscarmellose sodium, sodium laurilsulfate, lactose monohydrate,

anhydrous colloidal silica, magnesium stearate,

Coating: Hypromellose, polydextrose, titanium dioxide, macrogol 4000.

What Bicalutamide Teva looks like and contents of the pack

Bicalutamide Teva 50 mg Film-coated Tablets are white to off-white biconvex film-coated tablets, debossed with "93" on one side and "220" on the other.

Package sizes: 20, 28, 30, 40, 50, 56, 60, 84, 90 and 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Teva Pharma B.V.,
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturers

Teva UK Ltd.,
Brampton Road,
Hampden Park,
Eastbourne,
East Sussex,
BN22 9AG
England

Pharmachemie B.V.,
Swensweg 5,
PO Box 552,
2003 RN Haarlem,
The Netherlands

Galien LPS,
Rue Bellocier,
89107 Sens,
France

Teva Pharmaceutical Works Private Limited Company,
Pallagi ut 13,
Debrecen,
Hungary

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

Austria	Bicalutamid Teva 50 mg Filmtabletten
Belgium	Bicalutamide Teva 50 mg filmomhulde tabletten
Czech Republic	Bicaluplex 50 mg
Denmark	Bicalutamide Teva
Estonia	Bicalutamide-Teva
France	BICALUTAMIDE TEVA 50 mg, comprimé pelliculé
Germany	Bicalutamid Teva 50 mg Filmtabletten
Greece	Bicalutamide Teva 50 mg
Ireland	Bicalutamide Teva 50 mg Film-coated Tablets
Italy	Bicalutamide Teva 50 mg, comprese rivestite con film
Latvia	BICALUTAMIDE-TEVA 50 mg apvalkotās tabletes
Lithuania	Bicalutamide-Teva 50 mg plėvele dengtos tabletės
Luxembourg	Bicalutamide Teva 50 mg comprimés pelliculés
Netherlands	Bicalutamide 50 PCH, filmomhulde tabletten 50 mg
Norway	Bicalutamide Teva 50 mg filmdrasjert tablet
Poland	Bicalutamide Teva, 50 mg, tabletki powlekane
Portugal	Bicalutamida Teva 50mg comprimido revestido por película
Slovakia	Bicalutamid-Teva 50 mg
Slovenia	Bikalutamid Teva 50 mg filmsko obložene tablete
Sweden	Bicalutamide Teva 50 mg filmdragerade tabletter
United Kingdom	Bicalutamide 50 mg film coated tablets

This leaflet was last revised in June 2019.



AAAL4257