

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with
a doctor's prescription only

Bicalutamide Teva 150 mg

Tablets

Composition:

Each tablet contains:

Bicalutamide 150 mg

For information about inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

This medicine is not intended for women or children, including pregnant and breastfeeding women.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of prostate cancer.

Therapeutic group

An anti-androgenic agent that interferes with some of the activities of androgens (male hormones) within the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient bicalutamide or to any of the additional ingredients contained in the medicine (see section 6 – "Further Information").
- You are a woman.
- You are already taking a medicine called cisapride or certain antihistamine medicines (terfenadine, astemizole).

The medicine must not be given to children.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

Special warnings regarding use of the medicine:

Tell the doctor or pharmacist if:

- You suffer from liver problems. Your doctor may refer you for blood tests before and during the treatment with Bicalutamide Teva 150 mg.
- You suffer from heart or blood vessel problems, including heart rhythm disorders (arrhythmias), or if you are being treated with medicines for any of these conditions. The risk of heart rhythm disorders may increase as a result of taking Bicalutamide Teva 150 mg.
- You and/or your partner should use birth control while taking the medicine and for 130 days after stopping. Consult your doctor if you have any questions about birth control.
- If you are admitted to hospital, inform the medical staff that you are taking Bicalutamide Teva 150 mg.

Exposure to sunlight or ultraviolet (UV) light

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

Children and adolescents

Bicalutamide Teva 150 mg is forbidden to use in children and adolescents.

Tests and follow-up

Your doctor may refer you for blood tests to check for any changes caused to your blood.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Bicalutamide Teva 150 mg may affect the way certain medicines work, and certain medicines may affect the way Bicalutamide Teva 150 mg works.

Do not take Bicalutamide Teva 150 mg if you are taking any of the following medicines:

- Cisapride (for certain cases of indigestion).
 - Certain antihistamine medicines (terfenadine, astemizole).
- Bicalutamide Teva 150 mg may interfere with some medicines for treatment of heart rhythm problems (e.g., quinidine, procainamide, amiodarone, disopyramide, dofetilide, ibutilide, sotalol) or may increase the risk of heart rhythm problems when taken at the same time with other medicines such as:
- Methadone (for treatment of pain and drug addiction detoxification)
 - Moxifloxacin (an antibiotic)
 - Antipsychotics (for treatment of serious mental illnesses).

Tell your doctor or pharmacist if you are taking:

- Medicines taken by mouth to prevent blood clots. Anticoagulants and blood thinners. The doctor may refer you for blood tests before and during treatment with Bicalutamide Teva 150 mg
- Midazolam (for sedation or treatment of seizures)
- Ciclosporin (to suppress the immune system)
- Calcium channel blockers (to treat hypertension or certain heart diseases)
- Cimetidine (for stomach problems)
- Ketoconazole (to treat fungal infections)

Pregnancy, breastfeeding and fertility
Bicalutamide Teva 150 mg must not be used in women.

Driving and operating machinery

Bicalutamide Teva 150 mg is not likely to affect your ability to drive or use tools or machinery.

However, some patients may occasionally feel sleepy while taking Bicalutamide Teva 150 mg. If you feel sleepy, consult your doctor.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium-free.

Bicalutamide Teva 150 mg contains lactose. If you have been told by your doctor that you have an intolerance to certain types of sugar, consult with the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the preparation.

The dosage and treatment regimen will be determined by the doctor only.

- The usual dosage is generally one tablet per day.
- **Do not exceed the recommended dose.**
- Swallow the tablet whole with water.
- It is preferable to take the tablet at the same time every day.
- Do not chew or crush the tablets!
- Do not halve the tablet in the absence of a score line.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you accidentally took a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine

- If you forgot to take the medicine, skip the forgotten dose and take the next dose at the usual time.
- Do not take a double dose (two doses at the same time) to compensate for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Do not stop taking the medicine, even if you are feeling better, unless your doctor instructs you to stop.

Do not take medicines in the dark!

Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Bicalutamide Teva 150 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if the following side effects occur, you may need urgent medical treatment:

Allergic reactions

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

Symptoms may include sudden onset of:

- Skin rash, itching or hives.
- Swelling of the face, lips, tongue, throat or other parts of the body.
- Shortness of breath, wheezing or breathing difficulties.

Also refer to the doctor immediately if any of the following side effects occur:

Common side effects (effects that occur in 1-10 in 100 users):

- Yellowing of the skin or of the whites of the eyes (jaundice). These signs may be indicative of liver function disturbances, or in more rare cases (could affect 1 in 1,000 patients), of liver failure
- Abdominal pain
- Blood in the urine

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Severe shortness of breath or sudden worsening of shortness of breath, which may be accompanied by a cough or fever. These are signs of an inflammation of the lungs called interstitial lung disease

Side effects of unknown frequency (frequency cannot be determined from the available data):

- Changes in ECG (prolongation of QT interval)

Other possible side effects

Very common side effects (effects that occur in more than one user in 10):

- Skin rash
- Swelling and tenderness of the breasts
- Feeling weak

Common side effects (effects that occur in 1-10 in 100 users):

- Hot flushes
- Nausea
- Itching
- Dry skin
- Impotence, erectile problems
- Weight gain
- Reduced sex drive and reduced fertility
- Hair loss
- Hair re-growth or growth of extra hair
- Low level of red blood cells (anemia). This may make you feel tired or look pale
- Loss of appetite
- Depression
- Sleepiness
- Indigestion
- Dizziness
- Constipation
- Flatulence
- Chest pain
- Swelling

Rare side effect (effect that occurs in 1-10 in 10,000 users):

- Increased skin sensitivity to the sunlight

The doctor may refer you to carry out blood tests to check whether any changes were caused in the blood.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**
- Do not dispose of medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, Bicalutamide Teva also contains:

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulfate, colloidal silica anhydrous, magnesium stearate, povidone, polydextrose, titanium dioxide, hypromellose (hydroxypropyl methylcellulose), macrogol (polyethylene glycol).

What the medicine looks like and the contents of the package:

Bicalutamide Teva 150 mg

A round, convex, white, film-coated tablet, plain on one side and the letters "BCL" debossed on the other side.

Each package contains 28 or 30 tablets. Not all package sizes may be marketed.

Name of Manufacturer and License Holder and Address:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in May 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

140.83.31741

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