

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

The medicine is dispensed with  
a doctor's prescription only

# Bicalutamide Teva® 50 mg

## Tablets

### Composition:

#### Each tablet contains:

Bicalutamide 50 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 already taking a medicine called cisapride or certain antihistamine medicines (terfenadine, astemizole).
- You are a woman.

#### Special warnings regarding use of the medicine:

Before beginning treatment, tell the doctor if:

- 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 50 mg.
- You are taking blood thinners or medicines to prevent blood clots.
- You suffer from liver problems.
- You have diabetes and are taking "luteinizing hormone – releasing hormone (LHRH) analogs", including goserelin, buserelin, leuprorelin and triptorelin.
- You are admitted to hospital, inform the medical staff that you are taking Bicalutamide Teva 50 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.

#### Drug interactions

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** This is because Bicalutamide Teva 50 mg may affect the way certain medicines work, and certain medicines may affect the way Bicalutamide Teva 50 mg works. Do not take Bicalutamide Teva 50 mg if you are taking any of the following medicines:

- Cisapride (for certain cases of indigestion).
- Antihistamine medicines (terfenadine, astemizole).

Tell the doctor if you are taking:

- Medicines to treat heart rhythm disorders (e.g., quinidine, procainamide, amiodarone, sotalol).
- Bicalutamide Teva 50 mg could increase the risk of heart rhythm disorders if taken at the same time as medicines such as:
  - Methadone (for pain relief and part of drug addiction detoxification)
  - Moxifloxacin (an antibiotic)
  - Antipsychotics (for treatment of mental illnesses)
- Anticoagulants (taken by mouth), e.g., warfarin
- Ciclosporin (to suppress the immune system)
- Calcium channel blockers (to treat hypertension or heart conditions)
- Cimetidine (to lower gastric acidity)
- Ketoconazole (to treat infections caused by fungi)

#### Pregnancy, breastfeeding and fertility

Bicalutamide Teva 50 mg must not be used by women, including pregnant or breastfeeding women.

Bicalutamide Teva 50 mg may have an effect on male fertility which may be reversible.

#### Driving and operating machinery

Bicalutamide Teva 50 mg is not likely to affect your ability to drive or use tools or machinery. However, if you feel sleepy, exercise caution when performing these activities.

#### 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 50 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 dose 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.

#### 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. An overdose may lead to increased risk of bleeding.

#### If you forget 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.

Make sure to follow carefully the instructions regarding administration of the medicine, and in case of any doubt, ask the doctor.

**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 50 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:**

#### Allergic reactions

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

Symptoms may include sudden onset of:

- Skin rash, severe itching or hives on the skin (with raised lumps on the skin).
- 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:**

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

- Abdominal pain
- Blood in the urine

#### 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 rare cases (could affect 1 in 1,000 patients), of liver failure.

#### 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 (effects whose frequency has not been determined yet):

- Changes in ECG – a recording of electrical currents in the heart as detected by ECG (prolongation of QT interval).

#### Other possible side effects

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

- Dizziness
- Constipation
- Nausea
- Swelling and tenderness of the breast
- Hot flushes
- Feeling weak
- Swelling
- Low level of red blood cells (anemia); may cause tiredness or pallor

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

- Loss of appetite
- Reduced sex drive
- Depression
- Feeling sleepy
- Indigestion
- Swelling, flatulence
- Hair loss
- Hair re-growth or growth of extra hair
- Dry skin
- Itching
- Skin rash
- Impotence
- Weight gain
- Chest pain
- Reduced heart function
- Heart attack

#### Rare side effects (effects that occur 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](http://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.**
- **Store the medicine in the original packaging.**
- Do not dispose of medicines into 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, the medicine 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:

A round, white tablet, with the number "93" debossed on one side and "220" 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 Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva

This leaflet was revised in August 2021 according to MOH guidelines.

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

Bicalutamide Teva 50 mg:  
140.82.31740