**Teva Pharmaceuticals (Pty) Ltd**
Product name: Teva Bicalutamide
Dosage form and strength: Film-coated tablets; 50 mg & 150 mg

**PATIENT INFORMATION LEAFLET:**

**SCHEDULING STATUS:** S4

**TEVA BICALUTAMIDE 50** (Film-coated tablet)

Each film-coated tablet contains 50 mg bicalutamide

Contains sugar: 35 mg lactose monohydrate

**TEVA BICALUTAMIDE 150** (Film-coated tablet)

Each film-coated tablet contains 150 mg bicalutamide.Contains sugar: 105 mg lactose monohydrate

**Read all this leaflet carefully before you start taking TEVA BICALUTAMIDE.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TEVA BICALUTAMIDE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**WHAT IS IN THIS LEAFLET:**

## 1. WHAT TEVA BICALUTAMIDE IS AND WHAT IT IS USED FOR:

TEVA BICALUTAMIDE tablets are used in the treatment of advanced prostate cancer in men (in combination with hormones (LHRH analogue) therapy or surgical castration).

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TEVA BICALUTAMIDE:

**Do not take TEVA BICALUTAMIDE:**

- If you are hypersensitive (allergic) to bicalutamide or any of the other ingredients of TEVA BICALUTAMIDE.
- If you are a female, child, pregnant woman or breastfeeding mother.

**Warnings and precautions:**

***Take special care with TEVA BICALUTAMIDE:***

- if you have moderate to severe liver impairment your doctor will monitor your liver function during treatment with TEVA BICALUTAMIDE
- if you have non-alcoholic fatty liver disease (NAFLD) and associated liver disease
- if you are hospitalised warn the doctor that you are taking TEVA BICALUTAMIDE.

**Other medicines with TEVA BICALUTAMIDE:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking the following medicines:

- Ketoconazole (medicine used to treat fungal infections)
- Cimetidine (medicine for ulcers or heartburn)
- Anti-coagulants (medicines that prevent the blood from clotting).

**Pregnancy and breastfeeding:**

TEVA BICALUTAMIDE is contraindicated in pregnant and breastfeeding women.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

**Driving and using machinery:**

TEVA BICALUTAMIDE has no effect on the ability to drive or operate machinery.

**TEVA BICALUTAMIDE contains lactose.**

TEVA BICALUTAMIDE contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TEVA BICALUTAMIDE.

**TEVA 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 TEVA BICALUTAMIDE:

Do not share medicines prescribed for you with any other person.

Always take TEVA BICALUTAMIDE exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of TEVA BICALUTAMIDE is too strong or too weak, talk to your doctor or pharmacist.

TEVA BICALUTAMIDE 50:

*Adult males (including the elderly):*

The usual dose is one tablet (50 mg) once daily. Treatment with TEVA BICALUTAMIDE should be started at least three days prior to commencing treatment with a LHRH analogue, or at the same time as surgical castration.

TEVA BICALUTAMIDE 150:

*Adult males (including the elderly):*

The usual dose is one tablet (150 mg) once daily for two years or until progression.

**If you take more TEVA BICALUTAMIDE than you should:**

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

**If you forget to take TEVA BICALUTAMIDE:**

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

## 4. POSSIBLE SIDE EFFECTS:

TEVA BICALUTAMIDE can have side effects. Not all side effects reported for TEVA BICALUTAMIDE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEVA BICALUTAMIDE, please consult your doctor, pharmacist or other healthcare professional for advice.

**If any of the following happens, stop taking TEVA BICALUTAMIDE and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- infection (cough or hoarseness, fever, runny nose),
- unusual tiredness or weakness,
- shortness of breath or difficulty breathing,
- swelling of face, fingers, feet or lower legs,
- fever,
- bloody or black, tarry stools,
- blood in your urine,
- dark urine, 'flu-like' symptoms, gastrointestinal upset, yellow eyes, or skin,
- symptoms of non-alcoholic fatty liver disease like fatigue, pain, or weight loss, and over time inflammation of the liver.

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVA BICALUTAMIDE. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- constipation, diarrhoea, nausea, weakness,
- abdominal pain, bloated feeling, flatulence, or indigestion,
- chills, confusion, decrease or loss of appetite, dizziness, drowsiness,
- breast tenderness or swelling.

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following which may occur less frequently:**

- raised blood pressure,
- hot flushes,
- sore throat,
- tight chest,
- gastrointestinal or rectal bleeding (passing blood in stools),
- vomiting,
- hair loss,
- hair re-growth,
- sensitivity to light,
- headache,
- weight gain,
- erectile dysfunction.

**The following may also occur:**

- raised glucose levels,
- chest pain (arising from the heart),
- irregular heartbeat,
- sweating.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting F**orm, found online under SAHPRA's publications: **http://www.sahpra.org.za/Publications/Index/8.** By reporting side effects, you can help provide more information on the safety of TEVA BICALUTAMIDE.

## 5. HOW TO STORE TEVA BICALUTAMIDE:

- Store at or below 25 ºC. Do not remove blister from carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION:

**What TEVA BICALUTAMIDE contains:**

The active substance is bicalutamide.

TEVA BICALUTAMIDE 50: Each film-coated tablet contains 50 mg bicalutamide.

TEVA BICALUTAMIDE 150: Each film-coated tablet contains 150 mg bicalutamide.

Inactive ingredients: colloidal silica anhydrous, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry OY-GM-28900 white, povidone, purified water, sodium laurilsulfate.

**What TEVA BICALUTAMIDE looks like and contents of the pack:**

TEVA BICALUTAMIDE 50: White to off-white, film-coated round, biconvex tablet, debossed with '93' on one side and '220' on the other.

TEVA BICALUTAMIDE 150: White to off-white, film-coated round, biconvex tablet, one side debossed with 'BCL', plain on the other.

**Contents of the pack:**

- TEVA BICALUTAMIDE 50 tablets are packed into PVC/PVdC (transparent) and Al/PVC/PVdC blister strips in pack sizes of 28 or 30 tablets and the blister strips are packed into a carton.

- TEVA BICALUTAMIDE 150 tablets are packed into PVC/PVdC (transparent) and Al/PVC/PVdC blister strips in pack sizes of 28 or 30 tablets and the blister strips are packed into a carton.

**Holder of the Certificate of Registration:**

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