Applicant: Teva Pharmaceuticals (Pty) Ltd
Product name: BICALUTAMIDE 50/150 TEVA
Dosage form & strength: Each film-coated tablet contains 50 mg and 150 mg of bicalutamide, respectively
Registrat**ion** Numbers: 43/21.12/0764 ; 43/21.12/0765

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: S4

BICALUTAMIDE 50 TEVA (Film-coated tablet)

Each film-coated tablet contains 50 mg bicalutamide

Contains sugar: 35 mg lactose monohydrate

BICALUTAMIDE 150 TEVA (Film-coated tablet)

Each film-coated tablet contains 150 mg bicalutamide

Contains sugar: 105 mg lactose monohydrate

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BICALUTAMIDE TEVA 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 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 TEVA 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 BICALUTAMIDE TEVA:

Do not take BICALUTAMIDE TEVA:

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

Warnings and precautions:

Take special care with BICALUTAMIDE TEVA:

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

Other medicines with BICALUTAMIDE TEVA:

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:

BICALUTAMIDE TEVA 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:

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

BICALUTAMIDE TEVA contains lactose:

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 BICALUTAMIDE TEVA.

BICALUTAMIDE TEVA contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, essentially 'sodium-free'.

3. HOW TO TAKE BICALUTAMIDE TEVA:

Do not share medicines prescribed for you with any other person.
Always take BICALUTAMIDE TEVA 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 BICALUTAMIDE TEVA is too strong or too weak, talk to your doctor or pharmacist.

BICALUTAMIDE 50 TEVA:

Adult males (including the elderly):

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

BICALUTAMIDE 150 TEVA:

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 BICALUTAMIDE TEVA 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 BICALUTAMIDE TEVA:

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:

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

If any of the following happens, stop taking BICALUTAMIDE TEVA 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 BICALUTAMIDE TEVA. 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 Form**, 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 BICALUTAMIDE TEVA.

5. HOW TO STORE BICALUTAMIDE TEVA:

- 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 BICALUTAMIDE TEVA contains:

The active substance is bicalutamide.

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

BICALUTAMIDE 150 TEVA: 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 BICALUTAMIDE TEVA looks like and contents of the pack:

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

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

Contents of the pack:

- BICALUTAMIDE 50 TEVA 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.
- BICALUTAMIDE 150 TEVA 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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