APPROVED PATIENT INFORMATION LEAFLET

UPDATE ACCORDING TO DEC 2013 PIL GUIDELINE ***DATE SUBMITTED TO MCC: 5/02/2015***

MODULE 1.3.2– Patient Information Leaflet

Product proprietary name:	***Accord Bicalutamide 50 mg***
Dosage form and strength:	***50 mg Bicalutamide per Film Coated Tablet***
Applicant/PHCR:	***Accord Healthcare (Pty) Ltd***

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Accord Bicalutamide 50 mg (Film coated tablet)

Read all of this leaflet carefully before you start taking Accord Bicalutamide

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

Accord 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.

1. WHAT ACCORD BICALUTAMIDE CONTAINS:

Each tablet contains 50 mg bicalutamide.

Excipients

- Lactose monohydrate
- Sodium starch glycolate
- Povidone K -30
- Purified water
- Magnesium stearate
- Hypromellose E 5
- Titanium dioxide
- Polyethylene glycol 400

Amendments have been effected according to MCC recommendations, and the PIL is free of typographical and grammatical errors.

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2. WHAT ACCORD BICALUTAMIDE IS USED FOR:

Bicalutamide works by interfering with the actions of male sex hormones (androgens). It is used for the treatment of advanced prostate cancer in combination with hormone therapy or after surgery.

Ask your doctor or healthcare professional if you have any questions about why Accord Bicalutamide has been prescribed for you.

3. BEFORE YOU TAKE ACCORD BICALUTAMIDE:

DO NOT TAKE ACCORD BICALUTAMIDE IF:

Tell your doctor or healthcare professional if you have any of the following conditions or If you have ever experienced any of these conditions.

Before taking Accord Bicalutamide make sure your doctor or pharmacist knows:

- If you suffer from liver problems.
- If you have ever had an allergic reaction to this or any other medicine.
- If you are taking any other medicines, including those available without a prescription, herbal or complementary medicines.

4. HOW TO TAKE ACCORD BICALUTAMIDE:

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

Always take Accord Bicalutamide exactly as your doctor has instructed you. You should check with your doctor or pharmacist If you are unsure.

Your doctor will tell you how long your treatment with Accord Bicalutamide will last. If you have the impression that the effect of Accord Bicalutamide is too strong or too weak, tell your doctor or pharmacist.

- Take your medication exactly as directed by your doctor.

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- Swallow your tablet whole with a drink of water.
- Take this medicine at the same time each day to avoid missing any doses. If you do miss a dose, take it when you remember unless it is nearly time for your next dose. If your next dose is due, leave out the missed dose and take the next dose on time. Do not take two doses together.
- Do not stop taking Accord Bicalutamide without speaking with your doctor first.
- This medicine is for you. Never give it to others even if their condition appears to be the same as yours.
- Before taking any 'over-the-counter' medicines, check with your pharmacist which medicines are safe for you to take alongside Accord Bicalutamide.
- Keep your regular appointments with your doctor so your progress can be monitored. Accord Bicalutamide can cause changes to certain blood tests that your doctor may want to check.
- Before having any kind of surgery, including dental or emergency treatment, tell your surgeon, dentist or doctor that you are taking Accord Bicalutamide.

IF YOU TAKE MORE ACCORD BICALUTAMIDE THAN YOU SHOULD:

Never take more than the prescribed dose. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Where possible take the container with you, even if it is empty.

IF YOU FORGET TO TAKE ACCORD BICALUTAMIDE:

Do not take a double dose to make up for forgotten individual doses.

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5. POSSIBLE SIDE EFFECTS:

Accord Bicalutamide can have side effects.

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

Important: If you experience serious breathlessness, chest infection, swelling of your mouth or face, chest pain, blood in your urine, or yellowing of the skin and whites of your eyes, then contact your doctor straight away or go to the accident and emergency department of your local hospital.

Side effects are:

Feeling or being sick, diarrhoea

Other side-effects may include:

Weakness, breast tenderness, hot flushes, itchy dry skin, loss of hair, sweating, reduced sex drive, increased weight, decreased number of white blood cells, allergic reactions, lack of appetite (anorexia), increased blood sugar levels, depression, dizziness, drowsiness, sleeplessness, nervousness, confusion, abdominal pain, bloating, indigestion, constipation, nausea, vomiting, bleeding from the rectal passage, high blood pressure, increased frequency of urination at night, cough, sore throat, sneezing, fever, chills, flu-like symptoms, changes in your liver and liver failure.

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

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6. STORING AND DISPOSING OF ACCORD BICALUTAMIDE:

Store at or below 25 ˚C. Store in original package.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ACCORD BICALUTAMIDE:

Accord Bicalutamide 50 mg Tablets: 10 tablets per Clear PVC / PVdC-Aluminium blister strips, supplied in a pack size of 30.

8. IDENTIFICATION OF ACCORD BICALUTAMIDE:

White to off-white, round, biconvex, film coated tablets debossed 'B 50' on one side and plain on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

42/21.12/0431

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Accord Healthcare (Pty) Ltd

Tuscany Office Park,

6 Coombe Place, Rivonia,

Gauteng, South Africa

11. DATE OF PUBLICATION:

26 November 2010

5 February 2015

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