

## PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

**Bicalox 50 mg**  
**Bicalutamide**  
**Contains lactose.**

**Read all of this leaflet carefully before you start taking Bicalox 50 mg**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- Bicalox 50 mg 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 Bicalox is and what it is used for
2. What you need to know before you take Bicalox
3. How to take Bicalox
4. Possible side effects
5. How to store Bicalox
6. Contents of the pack and other information

### **1. What Bicalox is and what it is used for**

Bicalutamide belongs to a group of medicines called non-steroidal anti-androgen.

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 Bicalox has been prescribed for you.

## **2. What you need to know before you take Bicalox**

### **Do not take Bicalox**

-if you are hypersensitive (allergic) to bicalutamide or any of the other ingredients of Bicalox (listed in section 6).

-If you are taking any other medicines, including those available without a prescription, herbal or complementary medicines.

-Bicalutamide must not be given to females and children, pregnant women, or breastfeeding mothers.

### **Warnings and precautions**

Special care should be taken with Bicalox:

- If you suffer from liver problems. BICALOX 50 mg increases the risk of non-alcoholic fatty liver disease.
- Testosterone deficiency was associated with higher serum and hepatic levels of triglycerides and higher serum levels of low-density lipoprotein (LDL) in the body, with significant increases in fasting plasma glucose and insulin levels.
- Bicalox is associated with significant increase in incidences of other liver diseases such as cirrhosis, liver necrosis, and any liver disease.
- In patients with moderate to severe hepatic impairment. Periodic liver function testing should be considered during long term use.

### **Other medicines and Bicalox**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your health care provider if you are taking any of the following medicines:

- Ketoconazole and cimetidine
- Warfarin
- Midazolam

#### **Bicalutamide with food and drink**

Bicalutamide can be taken before, during or after a meal, but also you can take this medicine without food. The film coated tablet should be swallowed whole with some water.

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Bicalutamide is contraindicated in females and must not be given to pregnant women or breast-feeding mothers.

Bicalutamide may have an effect on male fertility which could be reversible.

#### **Driving and using machines**

Bicalox can affect your ability to drive, do not drive or use machines until the effects of Bicalox subsides.

#### **Bicalox contains lactose.**

Bicalox contains lactose monohydrate, which is a type of sugar.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Bicalox.

### **3. How to take Bicalox**

- **Do not share medicines prescribed for you with any other person.**
- **Always take Bicalox exactly as your doctor or pharmacist has told you.**  
**Check with your doctor or pharmacist if you are not sure.**
- **Your doctor will tell you how long your treatment with Bicalox will last. If you have the impression that the effect of Bicalox is too strong or too weak, tell your doctor or**

**pharmacist.**

The usual dose is one tablet each day.

Take your medication exactly as directed by your doctor. 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 Bicalox 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 Bicalox.

Keep your regular appointments with your doctor so your progress can be monitored. Bicalox can cause changes to certain blood tests that your doctor may want to check.

**If you take more Bicalox than you should**

Never take more than the prescribed dose. In the event of an overdose, 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 Bicalox**

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

**4. Possible side effects**

Bicalox can have side effects.

Not all side effects reported for Bicalox are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Bicalox, please consult your health care provider 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

These are frequent side effects:

- anaemia
- lack of appetite (anorexia)
- depression
- reduced sex drive
- dizziness
- drowsiness
- sleeplessness
- heart attack
- high blood pressure
- hot flushes
- cough
- sore throat

- sneezing
- fever
- chills
- flu-like symptoms
- abdominal pain
- bloating
- indigestion
- constipation
- nausea
- changes in your liver
- itchy dry skin
- loss of hair
- sweating
- rash
- development of breasts in males
- breast tenderness
- sexual inability
- Weakness

- increased weight

These are less frequent side effects:

- allergic reactions
- nervousness
- confusion
- bleeding from the rectal passage
- vomiting
- liver failure

These side effects have been reported but the frequency is unknown:

- decreased number of white blood cells
- increased blood sugar levels
- increased frequency of urination at night
- non-alcoholic fatty liver disease

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 or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Bicalox. You can also report side effects to Acino Pharma via email on [drugsafety\\_ZA@acino.swiss](mailto:drugsafety_ZA@acino.swiss). By reporting side effects you can help provide more information on the safety of Bicalox.

### **5.How to store Bicalox**

Store at or below 30 °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).

### **6.Contents of the pack and other information What Bicalox contains.**

The active substance is Bicalutamide.

#### **The other ingredients are:**

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

#### **What Bicalox looks like and contents of the pack**

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

Bicalox 50 mg Tablets: 10 tablets per Clear PVC / PVdC-Aluminium blister strips, supplied in a pack size

of 30.

**Holder of certificate of registration**

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