

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# BICALUTAMIDE 50 MG FILM-COATED TABLETS

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

### What is in this leaflet:

1. What bicalutamide is and what it is used for
2. What you need to know before you take bicalutamide
3. How to take bicalutamide
4. Possible side effects
5. How to store bicalutamide
6. Contents of the pack and other information

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

Bicalutamide 50mg film-coated Tablets (called bicalutamide throughout this leaflet) are used for the treatment of advanced prostate carcinoma. It is taken together with a drug known as a Luteinising Hormone-Releasing Hormone (LHRH) analogue – an additional hormone treatment – or with surgical removal of the testicles.

Bicalutamide is one of a group of medicines known as the non-steroidal anti-androgens. The active substance bicalutamide blocks the undesired effect of the male sex hormones (androgens) and inhibits cell growth in the prostate.

#### In a daily dose of 50 mg:

It is used in combination with other treatments such as drugs that reduce the androgen levels in the body.

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

#### **Do not take bicalutamide:**

- if you are allergic to the active substance or to any of the other ingredients of this medicine (listed in section 6)
- if you take terfenadine or astemizole (for hay fever or allergy) or cisapride (for stomach problems)
- Bicalutamide should not be given to women, including pregnant women or nursing mothers or to children or adolescents.

#### **Warnings and precautions**

#### **Talk to your doctor or pharmacist before taking bicalutamide**

- **if the liver is moderately or severely impaired.** The drug should only be taken after your doctor has carefully considered possible benefits and risks. If this is the case, your doctor will regularly perform tests of liver function (bilirubin, transaminases, alkaline phosphatase). If severe disturbances to liver function develop, treatment with bicalutamide should be discontinued.
- **If you have diabetes and are already taking an “LHRH analogue”.** These include goserelin, buserelin, leuprorelin and triptorelin.

### Other medicines and bicalutamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take bicalutamide together with any of the following medicines:

- Terfenadine or astemizole (for hay fever or allergy)
- Cisapride (for stomach problems)

If you take bicalutamide together with one of the following medicines, the effect of bicalutamide as well as the other medicine may be influenced. Please speak to your doctor before taking any of these medicines together with bicalutamide:

- Warfarin or any similar medicine to prevent blood clots
- Ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- Cimetidine (to treat stomach ulcers)
- Ketoconazole (used to treat fungal infections of the skin and nails)
- Calcium channel blockers (to treat high blood pressure)

#### **Taking bicalutamide with food, drink and alcohol**

Take one bicalutamide tablet, preferably at the same time of the day with or without food.

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

Bicalutamide is contra-indicated in women and must not be given to pregnant women or breast-feeding mothers.

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

There is a possibility that these tablets could make you feel dizzy or drowsy. If you are affected in this way, you should not drive or operate machinery.

#### **This product contains lactose**

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

### 3. HOW TO TAKE BICALUTAMIDE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The doctor prescribes an appropriate dosage for you personally. The recommended dosage is one tablet daily.

Tablets are swallowed whole with some liquid. Try to take the product at approximately the same time each day.

#### **If you take more bicalutamide than you should**

If you have taken too many tablets, contact your doctor or the nearest hospital as soon as possible. Take the remaining tablets or the pack with you so the doctor can identify what you have taken.

Primera barra LAETUS

36,7 mm

36,7 mm

Distancia al corte

36,7 mm

Primera barra LAETUS

36,7 mm

### **If you forget to take bicalutamide**

If you forget to take your daily dose, skip the missed dose and wait until the next administration time. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking bicalutamide**

Do not stop using the drug even if you feel healthy unless advised to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**You should contact your doctor straight away if you notice any of the following serious side effects:**

**Uncommon serious side effects** (may affect up to 1 in 100 people):

Serious allergic reaction which causes:

- Rash, itching or hives on the skin
- Swelling of the face, lips, tongue, throat or other parts of the body
- Shortness of breath, wheezing or trouble breathing

If this happens to you, **see a doctor straight away.**

Also tell your doctor straightaway if you notice any of the following side effects:

**Very common side effects** (may affect more than 1 in 10 people):

- Pain in your abdomen
- Blood in your urine

**Common side effects** (may affect up to 1 in 10 people):

- Yellowing of the skin or whites of the eyes (jaundice). These may be signs of liver problems or in rare cases (may affect up to 1 in 1,000 people) liver failure.

**Uncommon side effects** (may affect up to 1 in 100 people):

- Serious shortness of breath or shortness of breath which suddenly gets worse. This may be with a cough or high temperature (fever). These may be signs of an inflammation of the lungs called “interstitial lung disease”

Other possible side effects:

**Very common side effects** (may affect more than 1 in 10 people):

- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.
- Dizziness
- Constipation, feeling sick (nausea)
- Hot flushes
- Feeling weak, swelling
- Swelling and tenderness of your breasts.

**Common side effects** (may affect up to 1 in 10 people):

- Weight gain
- Feeling sleepy
- Indigestion, wind (flatulence)
- Hair loss, hair re-growth or growth of extra hair
- Skin rash, dry skin, itching
- Decreased appetite
- Chest pain

- Being unable to get an erection
- Reduced sex drive
- Depression
- Heart attack, reduced heart function
- Changes in liver enzymes

Your doctor may do blood tests to check for any changes to your blood.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE BICALUTAMIDE**

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month.

Do not use if you notice some visible signs of medicine deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

**What Bicalutamide 50mg film-coated tablets contain:**

- the active substance is bicalutamide. Each tablet contains 50mg bicalutamide
- the other ingredients are lactose monohydrate, povidone K-29/32, crospovidone type A, sodium lauryl sulphate, magnesium stearate, hypromellose, titanium dioxide (E171), macrogol 4000.

**What Bicalutamide 50mg film-coated tablets look like and contents of the pack**

White, round, biconvex film-coated tablets with “BCM 50” in one side.

Each pack contains 28 film-coated tablets in a blister pack.

**Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is:

Zentiva, One Onslow Street, Guildford, Surrey, GU1 4YS, UK

The Manufacturer is: Synthon BV., Microweg 22 - 6545 cm Nijmegen, The Netherlands or Synthon Hispania S.L., C/Castelló 1, Polígono las Salinas, 08830 Sant Boi de Llobregat (Barcelona), Spain

This leaflet was last revised in June 2013