

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Bicalutamide 50 mg film-coated tablets

**Read all of this leaflet carefully before you start using 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 is one of a group of medicines known as the non-steroidal antiandrogens.

Bicalutamide is used for the treatment of advanced prostate carcinoma. It is taken together with a drug known as a luteinising hormone-releasing hormone (LHRH) analogue which reduces the levels of androgens (male sex hormones) within the body, or with accompanying surgical removal of the testicles.

The active substance bicalutamide blocks the undesired effect of the male sex hormones (androgens) and inhibits cell growth in the prostate in this way.

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

##### **Do not take Bicalutamide**

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6)
- if you are already taking terfenadine or astemizole (for hay fever or allergy), or cisapride (for stomach disorders).

Bicalutamide should not be taken by women or must not be given to children and adolescents.

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Bicalutamide

- **if you have any heart or blood vessel conditions**, including heart rhythm problems (arrhythmia), or being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Bicalutamide.
- **if you are taking blood thinners or medicines to prevent blood clots**
- **if your liver function is moderately or severely impaired**. The drug should then 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.

- **if you have any questions about birth control.** You and/or your partner should use birth control while you are taking Bicalutamide and for 130 days after stopping Bicalutamide.

### **Children and adolescents**

Bicalutamide must not be given to children and adolescents.

### **Other medicines and Bicalutamide**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Bicalutamide can affect the way other medicines work. Also some other medicines can affect the way Bicalutamide works.

Do not take Bicalutamide if you are already taking any of the following medicines:

- cisapride (for stomach disorders)
- terfenadine or astemizole (for hay fever or allergy).

Bicalutamide might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

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 your immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- calcium channel blockers (used to treat high blood pressure or some heart conditions)
- cimetidine (used to treat stomach ulcers)
- ketoconazole (used to treat fungal infections of the skin and nails).

### **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 with some water or another liquid.

### **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**

Bicalutamide is unlikely to affect your ability to drive or to operate machinery. However, some people may occasionally feel drowsy when taking bicalutamide.

If you suffer from drowsiness you would be best advised not to carry out such tasks. However if you still drive a car or use machines you should exercise extra caution.

### **Sunlight or Ultraviolet (UV) light**

Avoid direct exposure to excessive sunlight or UV-light while you are taking Bicalutamide.

### **Bicalutamide 50 mg film-coated tablets contain lactose**

Bicalutamide 50 mg film-coated tablets contain lactose monohydrate, which is a type of sugar.

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor immediately.

### 3. How to take Bicalutamide

Always take this medicine exactly as described in this leaflet or 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 dose is one film-coated tablet once daily.

Try to take your tablet at the same time each day. Swallow the tablet whole with some liquid.

#### Use in children and adolescents

This medicine is not recommended for patients under the age of 18 years.

#### 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 with you the remaining tablets or the pack so the doctor can identify what you have taken.

#### If you forget to take Bicalutamide

If you forget to take your daily dose, skip it when you remember it and then take your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you are worried, ask your doctor or pharmacist for advice.

#### If you stop taking Bicalutamide

Do not stop taking your film-coated tablets even if you feel healthy unless so advised 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.

#### Allergic reactions

These are uncommon (may affect up to 1 in 100 users). The symptoms can include sudden onset of:

- 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 straight away if you notice any of the following:

**Very common** (may affect more than 1 in 10 users)

- pain in your abdomen
- blood in your urine.

**Common** (may affect up to 1 in 10 users)

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

**Uncommon** (may affect up to 1 in 100 users)

- 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'.

**Not known** (frequency cannot be estimated from the available data)

- changes in ECG (QT prolongation).

## **Other possible side effects:**

### **Very common** (may affect more than 1 in 10 users)

- dizziness
- constipation
- feeling sick (nausea)
- swelling and tenderness of your breasts
- hot flushes
- feeling weak
- swelling
- low levels of red blood cells (anaemia). This may make you feel tired and or look pale.

### **Common** (may affect up to 1 in 10 users)

- loss of appetite
- reduced sex drive
- depression
- feeling sleepy
- indigestion
- wind (flatulence)
- hair loss
- hair re-growth or growth of extra hair
- dry skin
- itching
- skin rash
- being unable to get an erection (impotence)
- weight gain
- chest pain
- reduced heart function
- heart attack.

### **Rare** (may affect up to 1 in 1000 users)

- increased skin sensitivity to sunlight.

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

Do not be concerned by this list of possible side effects. You may not get any of them.

## **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Bicalutamide**

Keep out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use Bicalutamide after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last day of that month.

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 contains**

- The active substance is bicalutamide. Each film-coated tablet contains 50 mg bicalutamide.
- The other ingredients are:  
Tablet core: lactose monohydrate, magnesium stearate, sodium starch glycolate Type A, povidone.  
Film coating: opadry II white (33F28627) containing hypromellose 6CP (E464), titanium dioxide (E171), macrogol 3000.

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

Bicalutamide 50 mg film-coated tablet is a white to off white, circular, biconvex, film-coated tablet debossed with '485' on one side and plain on the other side, and contains 50 mg bicalutamide.

Bicalutamide 50 mg film-coated tablets are available in packs of 28, 30 and 84 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Sun Pharmaceutical Industries Europe B.V.  
Polarisavenue 87  
2132 JH Hoofddorp  
The Netherlands

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Italy	Bicalutamide SUN 50 mg compresse rivestite con film
Netherlands	Bicalutamide SUN 50 mg filmomhulde tabletten
United Kingdom	Bicalutamide 50 mg film-coated tablets

**This leaflet was last revised in 02/2018.**