

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

### Bicalutamide 150 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 called non-steroidal anti-androgens.

Bicalutamide 150 mg can be used alone but can also be given as part of a combination treatment to patients that have had their prostate removed. Additionally in combination with radiation therapy for the treatment of prostate cancer, whereby the cancer has spread from the capsule of the prostate gland to the close surrounding tissue. These patients are at high risk for the cancer to spread.

The active substance bicalutamide blocks the undesired effect of a chemical made by a male sex gland (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 or adolescents.

##### **Warning 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 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. If severe disturbances to liver function develop, treatment with Bicalutamide should be discontinued.

- **if your blood still shows high levels of a certain protein used to detect prostate cancer** and the disease is still getting worse, bicalutamide treatment may need to be stopped.
- **if you have any questions about birth control.** You and/or your partner should use birth control while you are taking Bicalutamide SUN and for 130 days after stopping Bicalutamide SUN.

### **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.

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

Bicalutamide 150 mg may induce a period of subfertility or infertility in man.

### **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 150 mg film-coated tablets contain lactose**

Bicalutamide 150 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 recommended dose is one 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 wait until the next administration 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:**

##### **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.
- pain in your abdomen
- blood in your urine.

##### **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)

- skin rash
- swelling and tenderness of your breast tissue
- feeling weak.

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

- hot flushes
- feeling sick (nausea)
- itching
- dry skin
- problems getting an erection (erectile dysfunction)
- putting on weight
- reduced sex drive and reduced fertility
- hair loss
- hair re-growth or growth of extra hair
- low levels of red blood cells (anaemia). This may make you feel tired or look pale.
- loss of appetite
- depression
- feeling sleepy
- indigestion
- dizziness
- constipation
- wind (flatulence)
- chest pain
- swelling.

**Rare** (may affect up to 1 in 1,000 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 medicine 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 150 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 (E 171), macrogol 3000.

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

Bicalutamide 150 mg film-coated tablet is a white to off white, circular, biconvex, film-coated tablet debossed with '507' on one side and plain on the other side, and contains 150 mg bicalutamide.

Bicalutamide 150 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 150 mg compresse rivestite con film  
United Kingdom      Bicalutamide 150 mg film-coated tablets

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