

## Package leaflet: Information for the user

### Bicalutamide 150 mg film-coated tablets Bicalutamide

**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 150 mg is and what it is used for
2. What you need to know before you take Bicalutamide 150 mg
3. How to take Bicalutamide 150 mg
4. Possible side effects
5. How to store Bicalutamide 150 mg
6. Contents of the pack and other information

#### 1. What Bicalutamide 150 mg is and what it is used for

Bicalutamide 150 mg film-coated tablets (called Bicalutamide 150 mg throughout this leaflet) contains a medicine called bicalutamide. This belongs to a group of medicines called ‘anti-androgens’. Anti-androgens act against the effects of androgens (male sex hormones).

- It is used to treat prostate cancer.
- It works by blocking the effects of male hormones such as testosterone.

#### 2. What you need to know before you take Bicalutamide 150 mg

##### Do not take Bicalutamide 150 mg:

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- if you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole).
- if you are a woman.

Do not take Bicalutamide 150 mg if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Bicalutamide 150 mg.

Bicalutamide 150 mg must not be given to children.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Bicalutamide 150 mg:

- if you have problems with your liver. Your doctor may do blood tests before and during your treatment with bicalutamide 150 mg.
- if you have any of the following: any heart or blood vessel conditions,

including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Bicalutamide 150 mg.

If you go into hospital, tell the medical staff that you are taking Bicalutamide 150 mg.

#### Other medicines and Bicalutamide 150 mg

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

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 illness).

Also, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants). Your doctor may do blood tests before and during your treatment with bicalutamide.
- Ciclosporin (to suppress your immune system).
- Calcium channel blockers (to treat high blood pressure or some heart conditions).
- Cimetidine (for stomach problems).
- Ketoconazole (to treat infections caused by a fungus).

#### Pregnancy and breast-feeding

- Bicalutamide 150 mg must not be given to a woman.

#### Driving and using machines

- Bicalutamide is not likely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel sleepy while taking bicalutamide. If this happens to you, ask your doctor or pharmacist for advice.

#### Sunlight or Ultraviolet (UV) light

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

#### Bicalutamide 150 mg contains lactose

Bicalutamide 150 mg contains lactose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

#### 3. How to take Bicalutamide 150 mg

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 recommended dose for an adult is one tablet each day.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.
- Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

#### If you take more Bicalutamide 150 mg than you should

If you take more bicalutamide than you should, talk to a doctor or go to a hospital straight away.

#### If you forget to take Bicalutamide 150 mg

If you forget to take a dose, skip the missed dose and take the next dose as usual.

- Do not take a double dose (two doses at the same time) to make up for a forgotten dose

#### 4. Possible side effects

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

Some of these effects may be serious and may require medical attention.

**Uncommon:** may affect up to 1 in 100 people

#### Allergic reactions :

- 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, stop taking this medicine and **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 people

- Yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or in rare cases (affects less than 1 in 1,000 people) liver failure.
- Pain in your abdomen.
- Blood in your urine.

**Uncommon:** 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’.

**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 people**

- Skin rash.

- Swelling and tenderness of your breasts.
- Feeling weak.

**Common: may affect up to 1 in 10 people**

- 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 people**

- 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 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**For the UK:**

You can report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

**For Ireland:**

You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

**5. How to store Bicalutamide 150 mg**

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 blister and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice any visible signs of 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 150 mg film-coated tablets contains**

- The active substance is bicalutamide. Each film-coated tablet contains 150 mg bicalutamide.

- The other ingredients are:

Tablet core: Lactose monohydrate, Sodium starch glycolate (TypeA), Silica, colloidal anhydrous, Povidone K30, Magnesium stearate.

Film-coating: Opadry White Y-1-7000 consist of: hypromellose 5 CP (E464), Macrogol 400 and Titanium dioxide (E171).

**What Bicalutamide 150 mg film-coated tablets look like and contents of the pack**

Bicalutamide 150 mg is supplied as white to off white, circular, film coated biconvex tablets, debossed with 'DB04' on one side and plain on other side.

The blister pack strips comprising of 10 and 14 tablets to give pack sizes of 28, 30, 50, 60, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

**For UK:**

**Fresenius Kabi Oncology Plc**  
Lion Court, Farnham Road  
Bordon, Hampshire, GU35 0NF  
United Kingdom

**For IRL :**

Fresenius Kabi Deutschland GmbH  
Else-Kröner-Straße 1,  
61352 Bad Homburg v.d.Höhe  
Germany

**Manufacturer:**

Fresenius Kabi Oncology Plc.  
Lion Court, Farnham Road  
Bordon, Hampshire,  
GU35 0NF United Kingdom

Fresenius Kabi Deutschland GmbH  
Pfungstweide 53  
61169 Friedberg  
Germany

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

Austria	Bicalutamid Kabi 150 mg Filmtabletten
Bulgaria	Bicalutamide Kabi 150 mg film-coated tablets
Hungary	Bicalutamid Kabi 150 mg filmtabletta
Ireland	Bicalutamide 150 mg film-coated tablets
Poland	Bicalutamid Kabi
Portugal	Bicalutamida Kabi
Slovenia	Bikalutamid Kabi 150 mg filmsko obložene tablete
UK	Bicalutamide 150 mg film-coated tablets

**This leaflet was last revised in February 2019**