

## Package leaflet: Information for the user

### **Bilumide 50 mg, filmomhulde tabletten** 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 Bilumide 50 mg, **filmomhulde tabletten** is and what it is used for
2. What you need to know before you take Bilumide 50 mg, **filmomhulde tabletten**
3. How to take Bilumide 50 mg, **filmomhulde tabletten**
4. Possible side effects
5. How to store Bilumide 50 mg, **filmomhulde tabletten**
6. Contents of the pack and other information

#### **1. What Bilumide 50 mg, filmomhulde tabletten is and what it is used for**

Bilumide 50 mg, **filmomhulde tabletten** is one of a group of drugs called anti-androgens. It interferes with some of the actions of the male sex hormones.

Bilumide 50 mg used to treat prostate cancer. It is used as combination therapy in tumor stages called 'advanced' together with other treatments such as surgical castration or drugs which reduce the levels of androgens in the body.

#### **2. What you need to know before you take Bilumide 50 mg, filmomhulde tabletten**

##### **Do not take Bilumide 50 mg, filmomhulde tabletten**

- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman, a child or an adolescent.
- if you are taking any medications containing terfenadine, astemizole or cisapride (see 'Other medicines and Bilumide 50 mg, filmomhulde tabletten', below).

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

Talk to your doctor or pharmacist before taking Bilumide 50 mg:

- if you have any liver problems. Bicalutamide levels in your blood could be increased. It is possible that your liver function is tested periodically.
- if you have diabetes.

Please tell your doctor 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 Bilumide 50 mg.

##### **Other medicines and Bilumide 50 mg, filmomhulde tabletten**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to mention if you are taking any of the following:

- terfenadine or astemizole (for hay fever or allergy) or cisapride (for stomach disorders). See 'Do not take Bilumide 50 mg, filmomhulde tabletten'.
- 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)
- calcium channel blockers (to treat high blood pressure or some heart conditions)
- cimetidine (to treat stomach ulcers)
- ketoconazole (used to treat fungal infections of the skin and nails)

Bilumide 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).

### **Pregnancy and breast-feeding**

Bilumide 50 mg, filmomhulde tabletten is not to be used by women. Hence, Bilumide 50 mg must not be taken by women, including pregnant women or mothers who are breast-feeding.

### **Driving and using machines**

These tablets could make you feel dizzy or drowsy. If you are affected in this way you should not drive or operate machinery.

### **Bilumide 50 mg contains lactose**

One Bilumide 50 mg filmomhulde tabletten contains 58.6 mg lactose, a type of sugar. 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 Bilumide 50 mg, filmomhulde tabletten**

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

Depending on your condition, the usual dose is one 50 mg tablet daily.

- Swallow the tablet whole with a drink of water.
- You can take these tablets with or without food.
- Try to take your tablet at the same time each day.

### **If you take more Bilumide 50 mg, filmomhulde tabletten than you should**

Tell your doctor or contact your nearest hospital casualty department immediately. If possible, take your tablets or the box with you to show the doctor what you have taken.

### **If you forget to take Bilumide 50 mg, filmomhulde tabletten**

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

### **If you stop taking Bilumide 50 mg, filmomhulde tabletten**

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you.

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.

### **Serious side effects:**

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

**effects.**

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

- Yellowing of the skin or whites of the eyes caused by liver problems or in rare cases (may affect up to 1 in 1,000 people) liver failure

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

- Serious allergic reaction which causes swelling of the face or throat, or severe itching of the skin with raised lumps.
- Serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. Some patients taking Bilumide 50 mg get an inflammation of the lungs called interstitial lung disease.

**Other side effects:**

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

- tender or enlarged breast tissue
- weakness
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.
- hot flushes
- dizziness
- abdominal pain, constipation, nausea (feeling sick)
- oedema
- blood in urine

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

- loss of appetite
- decreased libido
- problems getting an erection (erectile dysfunction)
- depression
- drowsiness
- somnolence
- indigestion, flatulence (wind)
- hair loss, excessive body hair
- dry skin, itching
- increased weight
- blood tests which show changes in the way the liver is working
- heart attack, heart failure
- chest pain
- skin rash

**Rare side effects (may affect up to 1 in 1.000 people):**

- photosensitivity

**Side effects with unknown frequency:**

- changes in ECG (QT prolongation)

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 national reporting system listed in AppendixV\*. By reporting side effects can help provide more information on the safety of this medicine.

**5. How to store Bilumide 50 mg, filmomhulde tabletten**

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 and blister 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 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 Bilumide 50 mg, filmomhulde tabletten contains**

- The active substance is bicalutamide. Each tablet contains 50 mg bicalutamide.
- The other ingredients are:

Tablet core:

Povidone (K-30) (E1201)

Sodium laurilsulfate

Lactose monohydrate

Sodium starch glycolate Type A

Silica, colloidal anhydrous (E551)

Magnesium stearate (E572)

Film coat:

Hypromellose (E464)

Titanium dioxide (E171)

Polydextrose (E1200)

Triethylcitrate (E1505)

Macrogol

### **What Bilumide 50 mg, filmomhulde tabletten looks like and contents of the pack**

Bilumide 50 mg filmomhulde tabletten are white film-coated tablets with "BIC 50" printed on side.

Bilumide 50 mg filmomhulde tabletten are available in packs of 28 film-coated tablets

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

Bennett Pharmaceuticals S.A.

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RVG Number 34228

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