

## **Package leaflet: Information for the user**

### **Casomide 50mg 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, please 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**

The name of your medicine is Casomide 50 mg film-coated tablets. For convenience they will be called Casomide tablets in this leaflet.

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

#### **1. What Casomide tablets are and what they are used for**

Casomide tablets (daily dose 50 mg) are used for the treatment of advanced prostate cancer. It is taken together with a drug known as a luteinising hormone-releasing hormone (LHRH) analogue - an additional hormone treatment - or with accompanying surgical removal of the testicles.

In patients with locally advanced prostate cancer who are at high risk for disease progression, Casomide tablets (daily dose 150 mg) are used either alone or as additional (adjuvant) treatment following surgical removal of the entire prostate (radical prostatectomy) or radiotherapy.

Bicalutamide is one of a group of medicines known as the non-steroidal antiandrogens. 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 Casomide tablets**

##### **DO NOT take Casomide tablets if:**

- You are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- You have had any problems with your liver in the past from taking bicalutamide tablets.
- You take terfenadine (for hay fever or allergy), astemizole (for hay fever or allergy) or cisapride (for stomach disorders).

Casomide tablets should not be taken by women or given to children and adolescents.

Tell your doctor if you are not sure about any of the above.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Casomide if:

- **your liver function is moderately or severely impaired.** The medicine 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 Casomide tablets should be discontinued.

- **your renal function is severely impaired.** The medicine should then only be taken after your doctor has carefully considered possible benefits and risks.
- you have 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. If this is the case, your doctor should regularly monitor your heart function.
- **you have diabetes and are already taking a “LHRH analogue”**

### **Other medicines and Casomide**

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

Casomide tablets may not be used together with any of the following medicines:

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

If you take Casomide tablets 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 Casomide tablets:

- 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)
- Ca-channel-blockers (to treat high blood pressure)
- midazolam (used e.g. for preoperative sedation).

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).

### **Taking Casomide tablets with food and drink**

The tablets should be swallowed whole with a glass of water, with or without food.

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

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 women and must not be given to pregnant 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.

### **Casomide tablets contain lactose**

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

### **3. How to take Casomide tablets**

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

The recommended dose is 1 tablet per day (corresponding to 50 mg bicalutamide) or 3 tablets per day (corresponding to 150 mg bicalutamide). Tablets are swallowed whole with a glass of water.

Try to take the medicine approximately at the same time every day in order not to forget it.

#### **If you take more Casomide tablets than you should**

If you accidentally take too many tablets, call your doctor straight away, or go to the nearest hospital casualty department. Always take any leftover tablets with you, as well as the container and this leaflet, so that the medical staff will know what you have taken.

#### **If you forget to take Casomide tablets**

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 stop taking Casomide tablets**

Do not stop taking the tablets without talking to your doctor first, unless you get a side effect – see section 4 below.

Do not stop using the medicine 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.

#### **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 (including liver failure, liver enlargement).

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

- Serious allergic reaction which causes swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing or breathing 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 Casomide tablets get an inflammation of the lungs called interstitial lung disease.

#### **Other side effects:**

Tell your doctor if any of the following side effects bother you:

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

- tender or enlarged breast tissue
- feeling weak
- reduced sexual desire, erection problems, impotence
- hot flush
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- dizziness
- constipation
- abdominal pain

- nausea (feeling sick)
- blood in the urine (haematuria)
- oedema (face, extremities, trunk)

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

- diarrhoea
- flatulence (wind)
- indigestion
- drowsiness
- depression
- skin rash, rash with nodules and flecks, itching, sweating, excessive body hair
- hair loss
- dry skin
- weight gain
- diabetes mellitus
- decreased appetite
- general pain, pelvic pain, chest pain (e.g. angina)
- chills
- blood tests which show changes in the way the liver is working
- heart attack (myocardial infarction)
- heart failure (which may be associated with breathlessness, especially on exertion, a fast heart beat, swelling in the limbs and mottling of the skin)

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

- weight loss
- high blood sugar
- difficulty in sleeping
- shortness of breath (dyspnoea)
- dry mouth, gastrointestinal disorder
- needing to urinate during the night (nocturia)
- headache, back pain, neck pain

**Rare side effects** (may affect up to 1 in 1,000 people):

- vomiting
- increased skin sensitivity to sunlight

**Very rare side effects** (may affect up to 1 in 10,000 people):

- irregular heartbeat, abnormal ECG heart tracing
- reduction in blood platelets which increases risk of bleeding or bruising

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

- changes in ECG (QT prolongation)

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 HPRa 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). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Casomide tablets**

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

This medicine does not require any special storage conditions.

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

Do not throw away 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 Casomide tablets contain**

The active substance is bicalutamide. One film-coated tablet contains 50 mg bicalutamide.

The other ingredients are:

Core: Lactose monohydrate, sodium starch glycolate (type A), povidone K30, magnesium stearate.

Film-coating: Titanium dioxide (E171), hypromellose, macrogol 400.

### **What Casomide tablets look like and contents of the pack**

Film coated tablet.

Casomide 50 mg tablets are white, round and biconvex. The tablets are packaged in blisters consisting of plastic and aluminium foil.

Casomide 50 mg film coated tablet is available:

Pack sizes of 7, 10, 14, 15, 28, 30, 50, 56, 60, 84, 90 or 100 film coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### **Manufacturer**

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Centrafarm Services B.V., Nieuwe Donk 9, 4879 AC Etten Leur, Holland

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Austria	Bicalutamid Stada 50 mg Filmtabletten
Belgium	Bicalutamide EG <sup>®</sup> 50 mg filmomhulde tabletten
Denmark	Bicalustad
France	BICALUTAMIDE EG 50 mg, comprimé pelliculé
Germany	Bicalutamid STADA 50 mg Filmtabletten
Ireland	Casomide 50 mg film-coated tablets
Italy	BICALUTAMIDE EUROGENERICI 50 mg compresse rivestite con film
Luxembourg	Bicalutamide EG <sup>®</sup> 50 mg comprimés pelliculés
Netherlands	Bicalutamide CF 50 mg, filmomhulde tabletten
Portugal	Bicalutamida Stada
Sweden	Bicalustad 50 mg filmdragerade tabletter

**This leaflet was last revised in March 2017.**