Package leaflet: Information for the patient

Bicalutamide Sandoz® 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 [nationally completed name] is and what it is used for

[nationally completed name] is one of a group of drugs called anti-androgens. It interferes with some of the actions of the male sex hormones.

[nationally completed name] is used to treat prostate cancer.It is used either as
- **monotherapy** in tumor stages called 'locally advanced' or 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 [nationally completed name]

Do not take [nationally completed name]
- if you are allergic (hypersensitive) to bicalutamide or any of the other ingredients of this medicine (listed in section 6.1).
- if you are a woman, a child or an adolesent.
- if you are taking any medications containing terfenadine, astemizole or cisapride (see 'Other medicines and [nationally completed name]', below).

Warnings and precautions
Talk to your doctor or pharmacist before taking [nationally completed name]:

- 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.
- if 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 [nationally completed name].
- if you are taking [nationally completed name], you and/or your partner should use birth control while you are taking [nationally completed name] and for 130 days after stopping [nationally completed name]. Talk to your doctor if you have any questions about birth control.

Other medicines and [nationally completed name]
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 [nationally completed name]'
- cyclosporin (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)
- Blood thinners or medicines to prevent blood clots such as warfarin. Your doctor may do blood tests before and during your treatment with [nationally completed name].

[nationally completed name] 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, breast-feeding and fertility
[nationally completed name] is not to be used by women.
[nationally completed name] can lead to limited fertility or infertility in men for a transient period of time.

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.

[nationally completed name] contains 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.

[nationally completed name] contains sodium:
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take [nationally completed name]

Always take [nationally completed name] 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 (combination therapy), or three 50 mg tablets once daily (monotherapy).
- Swallow the tablets whole with a drink of water.
- You can take these tablets with or without food.
- Try to take your tablets at the same time each day.

If you take more [nationally completed name] 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 [nationally completed name]
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 [nationally completed name]
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 affect 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 [nationally completed name] get an inflammation of the lungs called interstitial lung disease.

Not known (frequency can not be estimated from the available data):
- Changes in ECG (QT prolongation).

Other side effects:
The frequency of some side effects depends on if [nationally completed name] is used in combination therapy or in monotherapy.

Very common side effects (may affect more than 1 in 10 people):
- tender or enlarged breast tissue
- weakness
- skin rash - very common in monotherapy but common (may affect up to 1 in 10 people) in combination therapy
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness

Very common in combination therapy but common in monotherapy are:
- 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

Rare (may affect up to 1 in 1,000 people):
- increased skin sensitivity to sunlight.

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 Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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.

Do not store above 25°C.

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 [nationally completed name] contains

- The active substance is bicalutamide.
- Each film-coated tablet contains 50 mg of bicalutamide.
- The other ingredients are: *Tablet core:* lactose monohydrate, sodium starch glycolate Type A, povidone K 30 (E1201), maize starch and magnesium stearate (E572). *Tablet coating:* methylcellulose, titanium dioxide (E171) and triacetin (E1518).

What [nationally completed name] looks like and contents of the pack

Round and white film-coated tablet with a diameter of approximately 7 mm.

The carton boxes with PVC/ Aclar//Al blisters may contain 20, 28, 30, 50, 56, 60, 84, 90, 98 or 100 film-coated tablets.
The carton boxes with unit dose PVC/ Aclar//Al blisters may contain 50 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V, Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

In het register ingeschreven onder:
Bicalutamide Sandoz 50 mg, filmomhulde tabletten is in het register ingeschreven onder:
RVG 33519.

Dit geneesmiddel is goedgekeurd in de lidstaten van de EEA onder de volgende namen:

Oostenrijk:	Bicalutamid Sandoz 50 mg - Filmtabletten
België:	Bicalutamide Sandoz 50mg filmomhulde tabletten
Denemarken:	Bicalutamid Sandoz

Finland:	Bicalutamid Sandoz 50 mg tabletti, kalvopaallysteinen
Frankrijk:	BICALUTAMIDE Sandoz 50 mg, comprimé pelliculé
Griekenland:	Omidex
Italië:	IGREDEX
Nederland:	Bicalutamide Sandoz 50 mg, filmomhulde tabletten
Portugal:	Bicalutamida Sandoz
Roemenië:	Bicalutamida Sandoz 50 mg comprimate filmate
Slovenië:	Bikalutamid Lek 50 mg filmsko obložene tablete
Zweden:	Bicalutamid Sandoz, 50 mg filmdragerade tabletter

Deze bijsluiter is voor het laatst goedgekeurd in februari 2019.