

Consumer Medicine Information

BICALOX[®]

Bicalutamide 50 mg tablets

What is in this leaflet

This leaflet answers some of the common questions people ask about **BICALOX**. It does not contain all the information that is known about **BICALOX**. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **BICALOX** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Bicalox is used for

BICALOX 50 mg is used to treat locally advanced prostate cancer. **BICALOX** is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens can help the cancer cells to grow. BICALUTAMIDE interferes with some of the actions of these hormones. BICALOX is only be taken by men. You must follow all the directions given to you by your doctor.

They can differ from the information in this leaflet.

Your doctor can prescribe this medicine for another use. Always ask your doctor if you need more information.

BICALOX is not known to be addictive.

Before you use Bicalox

When you must not use it

Do not take BICALOX if you are a woman. Women do not get treated with BICALOX.

Do not give BICALOX to children. There is no experience of treating children with BICALOX

Do not take BICALOX if you are allergic to bicalutamide or any of the other ingredients in BICALOX.

Do not take BICALOX if you are taking cisapride or the antihistamines, terfenadine and astemizole.

Do not take BICALOX after the use by (expiry) date printed on the pack. It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take BICALOX if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to use it

You must tell your doctor if:

1. you have allergies to:

- bicalutamide, the active ingredient in BICALOX
- any of the other ingredients of BICALOX 50 mg listed at the end of this leaflet
- other anti-androgen medicines
- any other medicines
- any other substances, such as foods, preservatives or dyes.

If you have an allergic reaction, you may get skin rash, hay fever, or have difficulty breathing or feel faint.

2. you have liver problems

If you have problems with your liver, it may not be safe for you to take BICALOX.

Tell your doctor if you are taking any other medicines, including:

- cisapride (see When you must not use it)
- the antihistamines terfenadine and astemizole (see When you must not use it)
- medicines used to prevent blood clots, especially warfarin
- midazolam
- cyclosporin
- medicines used to treat high cholesterol
- calcium channel blockers
- carbamazepine
- quinidine
- antiviral medicines for HIV infection
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way BICALOX works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. If you have not told your doctor about any of these things, tell them before you take any BICALOX. Taking BICALOX, follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, you must ask your doctor or pharmacist for help.

Using Bicalox

How much to take

The usual adult dose is one 50 mg tablet taken each day.

Swallow your BICALOX tablet whole with a full glass of water.

When to take it

Take BICALOX before food, at about the same time each day.

How long to take it

Continue taking BICALOX for as long as your doctor or pharmacist tells you.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is 12 hours before the next dose is due. If it is less than 12 hours to the next dose do not take the dose you have missed.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

Overdose

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much BICALOX. Do this even if there are no signs of discomfort or poisoning.

While you are using Bicalox

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be seen.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking BICALOX.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking BICALOX.

If you go into hospital, please let the medical staff know you are taking BICALOX.

Things you must not do

Do not give BICALOX to anyone else, even if they have the same condition as you.

Do not take BICALOX to treat any other complaints unless your doctor tells you to.

Do not stop taking BICALOX, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how BICALOX affects you.

Some patients may feel dizzy or weak.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BICALOX.

BICALOX helps people with locally advanced prostate cancer, but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- breast tenderness or changes in breast size
- hot flushes or sweating
- itching or dry skin
- increased hairiness or hair loss

- aches or pains anywhere in your body
- nausea (feeling sick)
- constipation
- weight changes
- stomach pain
- unusual tiredness or weakness
- decrease in your sexual drive
- inability to get or maintain an erection.

These are possible side effects of BICALOX .Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- frequent urination
- shortness of breath and dizziness when exercising and looking pale (anaemia)
- excessive thirst with weight loss, and passing large amounts of urine.

These are all serious side effects. Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- chest pain
- blood in urine
- yellowing of the skin or eyes and dark coloured urine
- rash, hives or severe itching of the skin
- swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- swelling of other parts of the body including hands, feet or ankles
- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever.
- shortness of breath, wheezing or trouble breathing.

These are all serious side effects. You may need urgent medical attention or hospitalisation. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some people may get other effects while taking BICALOX.

After using it

Storage

Keep your BICALOX tablets in the blister foil until it is time to take them. If you take BICALOX out of the blister foil, it will not keep well.

Keep it in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days. Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What BICALOX looks like

BICALOX 50 mg tablets is a white to off-white, round film-coated biconvex tablets, engraved with 'BC 50' on one face and plain on the other. BICALOX tablets are packed in blister foils of 28 tablets.

Ingredients

Each BICALOX 50 mg tablet contains 50 mg of bicalutamide as the active ingredient, plus

- lactose
- sodium starch glycolate
- povidone
- magnesium stearate (E572)
- Opadry White Y-1-7000

BICALOX does not contain added sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer:

Douglas Manufacturing Ltd
Cnr Te Pai Pl and Central Park Drive
Lincoln
AUCKLAND

Date of preparation: October 2009