

# BICALOX™

Bicalutamide 50 mg film-coated tablets

## Consumer Medicine Information

### 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 is used in combination with other medicines 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 should only be taken by men.**

**You must follow all the directions given to you by your doctor.**

They may differ from the information in this leaflet.

Your doctor may prescribe this medicine for another use.

**Always ask your doctor if you need more information.**

BICALOX is not addictive.

BICALOX is only available with a doctor's prescription.

### Before you take it

*When you must not take it*

**Do not take BICALOX if you are a woman.**

Women are not normally treated with BICALOX.

**Do not give BICALOX to children.**

There is no experience of its use in children.

**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 take 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 listed at the end of this leaflet;
  - other anti-androgen medicines;
  - any other medicines; or
  - 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**

It may not be safe for you to take BICALOX if you have problems with your liver.
- 3. You have heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.**

The risk of you having further heart rhythm problems may increase if you are taking BICALOX.

### *Taking other medicines*

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

- cisapride (see When you must not take it);
- the antihistamines terfenadine and astemizole (see When you must not take 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; or
- 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.

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## How to take it

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**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.**

### *How much to take*

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

### *How and when to take it*

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

Take BICALOX about the same time each day.

BICALOX should be started at the same time as the other medicines you have been given for the treatment of prostate cancer.

It does not matter if you take BICALOX before, with or after food.

### *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.**

### *If you take too much (overdose)*

**Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone Australia 13 11 26), 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.**

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## While you are taking it

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### *Things you must do*

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

**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.

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## Side effects

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

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

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:**

- hot flushes or sweating;
- breast tenderness or changes in breast size;
- itching or dry skin, rashes;
- increased hairiness or hair loss;
- stomach pain or indigestion;
- nausea or vomiting;
- diarrhea or constipation;
- flatulence (wind);
- dry mouth;
- loss of appetite or weight changes;
- depression unusual tiredness or weakness;
- dizziness or light-headedness;
- difficulty sleeping;
- headache;

- chills;
- pelvic pain;
- decrease in your sexual drive;
- inability to get or maintain an erection; or
- photosensitivity reaction of skin.

These are possible side effects of BICALOX.

**Tell your doctor immediately if you notice any of the following:**

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

These side effects may be serious.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:**

- chest pain;
- 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; or
- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever; or
- 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.

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## After taking it

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### 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. Protect from light and moisture.**

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

**Do not leave it on a window sill 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 one-and-a-half 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.**

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## Product description

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### What BICALOX looks like

BICALOX™ 50 mg tablets are white to off-white, round film-coated, biconvex tablets, engraved with 'BC 50' on one face and plain on other.

BICALOX™ tablets are available in:

Blister packs of 28, 56\* or 98\* tablets (AUST R: 129117); and

Bottles containing 28\*, 100\* or 500\* tablets (AUST R: 129119).

\*Some of these presentations and pack sizes are not marketed.

### Ingredients

**Active ingredient:** bicalutamide.

**Inactive ingredients:**

- lactose monohydrate;
- sodium starch glycollate;
- povidone;
- magnesium stearate;
- hypromellose;
- titanium dioxide; and
- macrogol 400.

BICALOX does not contain:

- added sucrose;
- gluten;
- tartrazine or any other azo dyes.

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## Sponsor/ Marketing Authorisation Holder

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Bicalox™ 50 mg blister pack  
AUST R 129117

Bicalox™ 50 mg bottle AUST R  
129119

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