

# Bicalutamide AN tablets

*Bicalutamide*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some of the common questions people ask about BICALUTAMIDE AN. It does not contain all the information that is known about BICALUTAMIDE AN.

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 BICALUTAMIDE AN 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.

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### What BICALUTAMIDE AN is used for

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BICALUTAMIDE AN is used in combination with other medicines to treat advanced prostate cancer.

BICALUTAMIDE AN is an antiandrogen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow.

BICALUTAMIDE AN interferes with some of the actions of these hormones.

BICALUTAMIDE AN should only be taken by men.

**Follow all 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. Ask your doctor if you want more information.

BICALUTAMIDE AN is not addictive.

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### Before you take BICALUTAMIDE AN

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#### *When you must not use it*

**Do not take BICALUTAMIDE AN if you are a woman.**

Women are not normally treated with BICALUTAMIDE AN.

**Do not give BICALUTAMIDE AN to children.**

There is no experience of its use in children.

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

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

**Do not take BICALUTAMIDE AN 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 BICALUTAMIDE AN 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:**

- you have allergies to:**
  - bicalutamide, the active ingredient in BICALUTAMIDE AN
  - any of the other ingredients of BICALUTAMIDE AN 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 a skin rash, hay fever, or have difficulty breathing or feel faint.
- you have liver problems**

It may not be safe for you to take BICALUTAMIDE AN if you have problems with your liver.

#### *Taking other medicines*

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 BICALUTAMIDE AN work.

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 BICALUTAMIDE AN.

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## How to take BICALUTAMIDE AN

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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, ask your doctor or pharmacist for help.**

### *How to take it*

The usual adult dose is one 50 mg tablet taken each day. Swallow your BICALUTAMIDE AN whole with a full glass of water.

### *When to take it*

Take BICALUTAMIDE AN at about the same time each day.

BICALUTAMIDE AN 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 BICALUTAMIDE AN before, with or after food.

### *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.**

### *How long to take it*

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

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

**Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to the Accident Emergency Centre at your nearest hospital, if you or anyone else may have taken too much**

**BICALUTAMIDE AN. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## While you are taking BICALUTAMIDE AN

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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 BICALUTAMIDE AN.**

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

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

### *Things you must not do*

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

**Do not take BICALUTAMIDE AN to treat any other complaints unless your doctor tells you to.**

**Do not stop taking BICALUTAMIDE AN, or lower the dosage, without checking with your doctor.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how BICALUTAMIDE AN affect 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 BICALUTAMIDE AN.**

BICALUTAMIDE AN 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
- increased hairiness or hair loss
- stomach pain or indigestion
- nausea or vomiting
- diarrhoea 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

**These are possible side effects of BICALUTAMIDE AN.**

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

- 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 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
- 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 BICALUTAMIDE AN.

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## After taking BICALUTAMIDE AN

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### Storage

**Tablets in the blister foil until it is time to take them.**

If you take BICALUTAMIDE AN out of the blister foil, it will not keep well.

**Keep it in a cool dry place where the temperature stays below 25°C.**

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

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not keep outdated medicine or medicine no longer needed.

### 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 it looks like

BICALUTAMIDE AN 50 mg are white to off white, round, biconvex, film coated tablets debossed "B50" on one side and plain on other side containing 50 mg of Bicalutamide.

### Ingredients

#### Active Ingredient:

Each BICALUTAMIDE AN tablet contains 50 mg of Bicalutamide as the active ingredient, and the following inactive ingredients:

#### Other Ingredients:

- Lactose
- Povidone
- Sodium starch glycollate type A
- Magnesium stearate
- Hypromellose
- Macrogol 400
- Titanium dioxide

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

BICALUTAMIDE AN are presented in PVC/PVdC-Alu blisters. Each pack contains 28 tablets. AUST R 162831

### Name and Address of the Sponsor

**Amneal Pharma Australia Pty Ltd.**  
12 River St, South Yarra  
VIC 3141  
Australia

### Date of Preparation

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