

APO-BICALUTAMIDE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-BICALUTAMIDE?

APO-BICALUTAMIDE contains the active ingredient bicalutamide. Bicalutamide is used in combination with other medicines called LHRH agonists to treat advanced prostate cancer and to prevent a side effect of LHRH agonists.

For more information, see Section [1. Why am I using APO-BICALUTAMIDE?](#) in the full CMI.

2. What should I know before I use APO-BICALUTAMIDE?

Do not use if you have ever had an allergic reaction to Bicalutamide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-BICALUTAMIDE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-BICALUTAMIDE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-BICALUTAMIDE?

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

More instructions can be found in Section [4. How do I use APO-BICALUTAMIDE?](#) in the full CMI.

5. What should I know while using APO-BICALUTAMIDE?

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|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-BICALUTAMIDE.• Be sure to keep all your appointments with your doctor so your progress can be checked.• Use adequate contraception while you are taking APO-BICALUTAMIDE and for at least 130 days after you have stopped taking APO-BICALUTAMIDE. |
| Things you should not do | <ul style="list-style-type: none">• Do not give APO-BICALUTAMIDE to anyone else, even if they have the same condition as you.• Do not take APO-BICALUTAMIDE to treat any other complaints unless your doctor tells you to.• Do not stop taking APO-BICALUTAMIDE, or lower the dosage, without checking with your doctor |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how APO-BICALUTAMIDE affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your APO-BICALUTAMIDE in the blister foil until it is time to take them.• Keep it in a cool, dry place where the temperature stays below 25°C. |

For more information, see Section [5. What should I know while using APO-BICALUTAMIDE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may be serious. Tell your doctor immediately if you have 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, 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.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-BICALUTAMIDE

Active ingredient: *bicalutamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-BICALUTAMIDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-BICALUTAMIDE.**

Where to find information in this leaflet:

- [1. Why am I using A APO-BICALUTAMIDE?](#)
- [2. What should I know before I use A APO-BICALUTAMIDE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-BICALUTAMIDE?](#)
- [5. What should I know while using APO-BICALUTAMIDE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-BICALUTAMIDE?

APO-BICALUTAMIDE contains the active ingredient bicalutamide. APO-BICALUTAMIDE is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells grow.

APO-BICALUTAMIDE interferes with some of the actions of these hormones. APO-BICALUTAMIDE is used in combination with other medicines called LHRH agonists to treat advanced prostate cancer and to prevent a side effect of LHRH agonists.

APO-BICALUTAMIDE should only be taken by men.

2. What should I know before I use APO-BICALUTAMIDE?

Warnings

Do not use APO-BICALUTAMIDE if:

- you are allergic to bicalutamide,
- any of the ingredients listed at the end of this leaflet.
- you are allergic to lactose

Some of the symptoms of an allergic reaction may include:

- cough, shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

- fainting or hayfever-like symptoms
- you are allergic to other anti-androgen medicines.

Do not take this medicine if you are taking cisapride, terfenadine or astemizole.

Do not take this medicine if you are female.

Women are not treated with this medicine, as it could cause major defects in unborn children if taken by pregnant women, or harm to infants if taken when breastfeeding

- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have any other medical conditions
- have liver problems
- have diabetes
- have heart conditions, including heart rhythm problems (arrhythmia)
- take any medicines for any other condition
- If you have allergies to medicines or substances such as foods, preservatives or dyes.

Tell your doctor if you are planning to start a family, as this medicine may affect your fertility.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take APO-BICALUTAMIDE if you are a woman.

APO-BICALUTAMIDE may also cause a period of low fertility or infertility whilst you are taking it and for a period afterwards. NOTE however that you may not be infertile. As APO-BICALUTAMIDE may affect your sperm, effective contraception must be used by you and/or your partner while you are taking APO-BICALUTAMIDE and for at least 130 days after you have stopped taking APO-BICALUTAMIDE.

Children

- Do not give APO-BICALUTAMIDE to children.
- There is no experience of its use in children.

3. What if I am taking other medicines?

Tell your doctor and pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APO-BICALUTAMIDE and affect how it works. These include:

- cisapride
- terfenadine, astemizole
- medicines used to prevent blood clots, especially warfarin
- cimetidine, used for stomach problems
- ketoconazole, used to treat fungal infections
- midazolam or carbamazepine, used for treating seizures
- cyclosporin, used after organ transplants
- statins used to treat high cholesterol (e.g. simvastatin, atorvastatin, pravastatin, rosuvastatin, simvastatin)
- calcium channel blockers used to treat high blood pressure (e.g. felodipine, nifedipine, amlodipine)
- quinidine, used to treat certain heart problems
- some medicines used to treat viral infections (e.g. ritonavir, saquinavir)
- other medicines which interfere with the liver's CYP450 enzyme system

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with bicalutamide.

4. How do I take APO-BICALUTAMIDE?

How much to take

- The usual adult dose is one 50 mg tablet taken each day. This dose may be reduced if you have severe liver problems
- Swallow your APO-BICALUTAMIDE tablet whole with a full glass of water.
- Follow the directions given to you by your doctor or pharmacist carefully, they may differ from the information contained in the leaflet.

How to take APO-BICALUTAMIDE

- Take APO-BICALUTAMIDE at about the same time each day.
- Taking it at the same time each day will have the best effect and will also help you remember when to take it. It does not matter if you take it with or without food.
- APO-BICALUTAMIDE 50 mg should be started at the same time as the other medicines you have been given for the treatment of prostate cancer.

How long to take APO-BICALUTAMIDE

- Continue taking APO-BICALUTAMIDE for as long as your doctor or pharmacist tells you.
- Make sure you have enough to last over weekends and holidays.

If you forget to use APO-BICALUTAMIDE

APO-BICALUTAMIDE should be used regularly at the same time each day. If you miss your dose at the usual time, 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 for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of unwanted side effects.

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

If you use too much APO-BICALUTAMIDE

If you think that you have used too much APO-BICALUTAMIDE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-BICALUTAMIDE?

Things you should do

- **Keep all your doctor's appointments, as your doctor may do tests to make sure the medicine is working and to prevent side effects.**
- **Tell any other doctors, dentists and pharmacists who are treating you that you are taking APO-BICALUTAMIDE.**
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking APO-BICALUTAMIDE.
- You will need to take another prostate cancer medicine (an LHRH agonist) whilst you are taking bicalutamide. The two medicines need to work together to have an effect.
- APO-BICALUTAMIDE may affect your sperm (semen) while you are taking it and for some time after you stop taking it. As a precaution, you and/or your partner must use adequate contraception while you are taking APO-BICALUTAMIDE and for at least 130 days after you have stopped taking APO-BICALUTAMIDE.

Remind any doctor, dentist or pharmacist you visit that you are using APO-BICALUTAMIDE.

Things you should not do

- Do not give APO-BICALUTAMIDE to anyone else, even if they have the same condition as you.
- Do not take APO-BICALUTAMIDE to treat any other complaints unless your doctor tells you to.
- Do not stop taking APO-BICALUTAMIDE, or change the dosage, without checking with your doctor.
- Do not take APO-BICALUTAMIDE if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-BICALUTAMIDE affects you.

Some patients may feel sleepy, dizzy or weak when taking this medicine.

Looking after your medicine

- **Keep your APO-BICALUTAMIDE tablets in the blister foil until it is time to take it.**

If you take APO-BICALUTAMIDE out of the blister foil, it may not keep well.

- **Keep your medicine in a cool dry place where the temperature will stay below 25°C.**

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- 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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects:

| Less serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> • Hot flushes or sweating • breast tenderness, changes in breast size or swelling • stomach pain or indigestion, • nausea or vomiting • diarrhoea or constipation, • unusual tiredness or weakness • dizziness or light-headedness • headache • chill • itching or dry skin, rashes • increased hairiness or hair loss • flatulence (wind) • dry mouth • loss of appetite or weight changes • depression • difficulty sleeping, feeling sleepy • pelvic pain • decrease in your sexual drive • inability to get or maintain an erection | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • chest pain, with or without a feeling of tightness radiating to the shoulders back, neck jaw or arms, with sweating, chills, nausea, vomiting and paleness • Yellowing of the skin or eyes and dark coloured urine (jaundice) • cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; rash, itching or hives on the skin; fainting; hayfever-like symptoms (signs of an allergic reaction) • serious breathlessness or sudden worsening of breathlessness, possibly with a cough or fever • frequent urination (including at night) blood in the urine • becoming out of breath and dizzy when exercising, looking pale (anaemia) • excessive thirst with weight loss, passing large amounts of urine, sweet smelling breath | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What APO-BICALUTAMIDE contains

| | |
|---|--|
| Active ingredient (main ingredient) | bicalutamide |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• lactose monohydrate• sodium starch glycollate type A• povidone• magnesium stearate• hypromellose• macrogol 400• titanium dioxide |
| Potential allergens | Lactose |

Do not take this medicine if you are allergic to any of these ingredients.

What APO-BICALUTAMIDE looks like

White to off white, round, biconvex, film coated tablets debossed "B50" on one side and plain on other side. Available in blister packs of 28 tablets.

AUST R 194683

Who distributes [medicine name]

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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