

APO-Bicalutamide Tablets

Contains the active ingredient bicalutamide

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about bicalutamide. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Bicalutamide. It contains the active ingredient bicalutamide.

It is used in combination with other medicines called LHRH agonists to treat advanced prostate cancer and to prevent a side effect of LHRH agonists.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

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 to grow.

Bicalutamide interferes with some of the actions of these hormones.

Bicalutamide should only be taken by men.

There is no evidence that this medicine is addictive.

Use in children

This medicine must not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are taking cisapride or the antihistamines terfenadine or astemizole.**
- **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.
- **You are below the age of 18 years.**
There is no experience of its use in children.

- **You are hypersensitive to, or have had an allergic reaction to bicalutamide or any of the ingredients listed at the end of this leaflet (including lactose).**

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 hay fever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency Department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - liver problems
 - diabetes, this medicine may affect how your sugar levels are controlled
 - heart 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 this medicine.
3. You are planning to start a family. This medicine may affect your fertility.
4. You are planning to have surgery or an anaesthetic or are going into hospital.
5. You are currently receiving or are planning to receive dental treatment.
6. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with bicalutamide. These include:

- cisapride (see "When you must not use it")
- antihistamines called terfenadine or astemizole (see "When you must not use it")
- medicines used to prevent blood clots, especially warfarin
- cimetidine, used to treat stomach problems
- ketoconazole, used to treat fungal infections
- midazolam, used to help people get to sleep, as an anaesthetic and for treating seizures
- cyclosporin, used after organ transplants
- medicines called statins used to treat high cholesterol (e.g. simvastatin, atorvastatin, pravastatin, lovastatin, rosuvastatin, simvastatin, fluvastatin)
- calcium channel blockers such as felodipine, nifedipine, nicardipine, amlodipine, used to treat high blood pressure and sometimes angina
- carbamazepine, used to control epilepsy

- quinidine, used to treat certain heart problems
- amprenavir, indinavir, nelfinavir, ritonavir, saquinavir or loviridine, medicines used to treat virus infections
- 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.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose for men is one 50 mg tablet each day. This may be reduced if you have severe liver problems.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow your tablet whole with a full glass of water.

When to take it

Start taking this medicine when you start taking the other medicines you have been given to treat prostate cancer.

Take this medicine at 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 before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose (i.e. less than 12 hours to the next dose), skip the missed dose and take your next dose at the usual time. Otherwise take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of unwanted side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Make sure to always take another prostate cancer medicine (called an LHRH agonist) during the time that you are taking bicalutamide. The two medicines need to work together to have an effect.

Your doctor may do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up, and keep any appointments the doctor has made for you.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking bicalutamide or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- hot flushes or sweating
- breast tenderness or swelling
- mild rash, itching or dry skin
- increased hairiness, or loss of hair
- stomach pain or indigestion
- nausea or vomiting
- diarrhoea or constipation
- wind
- dry mouth
- loss of appetite or weight changes
- depression
- unusual tiredness or weakness
- dizziness or light-headedness
- problems sleeping or feeling sleepy
- headache
- chills
- pelvic pain
- decrease in your sexual drive
- inability to get or maintain an erection.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention.

- frequent urination, including at night
- blood in the urine
- becoming out of breath and dizzy when exercising, and looking pale (anaemia)
- excessive thirst with weight loss and passing large amounts of urine, and/or sweet smelling breath.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency Department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to bicalutamide, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this 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

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Bicalutamide looks like

APO-Bicalutamide 50 mg tablets are white to off white, round, biconvex, film coated tablets

debossed "B50" on one side and plain on other side.

Ingredients

Each tablet contains 50 mg of bicalutamide as the active ingredient.

It also contains the following inactive ingredients:

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

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

APO-Bicalutamide is available in blister packs of 28 tablets.

Australian Registration Numbers

APO-Bicalutamide 50 mg Tablets
AUST R 194683

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, NSW 2113
Australia

APO and APOTEX are the registered trademarks of Apotex Inc.

This leaflet was prepared in April 2016.