

APO-Anastrozole Tablets

Contains the active ingredient anastrozole

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 anastrozole. 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.

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-Anastrozole. It contains the active ingredient anastrozole.

It is used to treat breast cancer in women who no longer have their menstrual periods either naturally, due to their age or after surgery, radiotherapy or chemotherapy.

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

Anastrozole is a non-steroidal aromatase inhibitor, which reduces the amount of oestrogen (female sex hormone) made by the body. In some types of breast cancer, oestrogen can help the cancer cells grow. By blocking oestrogen, anastrozole may slow or stop the growth of cancer.

There is no evidence that this medicine is addictive.

Use in children

Do not give anastrozole to a child.

Anastrozole is not recommended for use in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are pregnant.**
Anastrozole may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding.**
Anastrozole may pass into human breast milk.
- 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.
- **You are hypersensitive to or have had an allergic reaction to anastrozole, or any of the ingredients listed at the end of this leaflet.**

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.

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

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
 - Kidney problems
 - Osteoporosis, a family history of osteoporosis or risk factors for developing osteoporosis (such as smoking, a diet low in calcium, poor mobility, a slight build or treatment with steroid medicines) Aromatase inhibitors may decrease bone mineral density (BMD) in women who have been through menopause, with a possible increased risk of fractures. Your doctor should discuss with you your treatment options for managing this possible increased risk of fractures.
3. You are currently pregnant or you plan to become pregnant.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
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 anastrozole. These include:

- Tamoxifen, a medicine used to treat breast cancer
- Any medicine that contains oestrogen such as medicines used in Hormone Replacement Therapy (HRT) or oral contraceptives

- Any health food products that contain natural oestrogens used for post-menopausal symptoms.
- Medicines from a class called "Luteinising Hormone Releasing Hormone (LHRH) agonists", such as goserelin or leuprorelin.

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 anastrozole.

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 or pharmacist will tell you how many anastrozole tablets to take each day. This will depend on your condition and whether you are taking any other medicines.

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

How to take it

Swallow anastrozole tablets whole, with a glass of water.

When to take it

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 anastrozole before, with or after food.

How long to take it for

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

Do not stop taking it unless your doctor tells you to - even if you feel better.

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, 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 you experiencing 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 pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital

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 anastrozole affects you.

Some patients may occasionally feel weak or sleepy.

Possible side effects

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

This list includes the more common side effects. Mostly, these are mild:

- Hot flushes
- Feeling weak or a lack of energy
- Feeling sleepy
- Joint pain or stiffness
- Bone pain
- Arthritis
- Vaginal dryness
- Vaginal bleeding
- Thinning of hair (hair loss)
- Mild skin rash
- Feeling sick (nausea)

- Diarrhoea
- Headache
- Loss of appetite (anorexia)
- Vomiting
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of hand)
- Pins and needles
- Loss of taste or changing taste of food or drink

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. You may need urgent medical attention or hospitalisation.

- Sudden signs of allergy such as shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
- Severe skin reactions with lesions, ulcers or blisters.
- Liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes)

Anastrozole may be associated with changes in your blood, urine or liver.

Your doctor may want to perform tests from time to time to check on your progress and detect any side effects.

Uncommon side effects can include, trigger finger which is a condition in which one of your fingers or your thumb catches in a bent position.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Allergic reactions

If you think you are having an allergic reaction to anastrozole, 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
- hayfever-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 they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Anastrozole looks like

Anastrozole 1 mg is a white, round biconvex coated tablet, engraved

'APO' on one side, 'AN' over '1' on the other side.

Old Formulation

APO-Anastrozole 1 mg is a white, round biconvex coated tablet, engraved 'APO' on one side, 'AN' over '1' on the other side.

Blister pack of 30 tablets.

New Appearance and Formulation

APO-Anastrozole 1 mg is a white, round, biconvex tablet, debossed '1' on one side, plain on reverse.

Blister pack of 30 tablets.

Ingredients

Each Anastrozole tablet contains 1 mg of anastrozole as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate
- hypromellose
- hydroxypropyl cellulose
- titanium dioxide
- macrogol 8000.

Old Formulation

Each APO-Anastrozole tablet contains 1 mg of anastrozole as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate
- hypromellose
- hydroxypropyl cellulose
- titanium dioxide
- macrogol 8000.

New Appearance and Formulation

Each APO-Anastrozole tablet contains 1 mg of anastrozole as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- magnesium stearate
- sodium starch glycollate type A
- Opadry II white 85F18422.

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

Australian Registration Numbers

Old Formulation

APO-Anastrozole 1 mg tablet (blister pack): AUST R 198270

New Appearance and Formulation

APO-Anastrozole 1 mg film-coated tablet (blister pack): AUST R 266676

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in April 2017.