

AZASTROLE™

Anastrozole 1 mg film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about AZASTROLE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of taking AZASTROLE 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 your medicine.

You may need to read it again.

What AZASTROLE is used for

AZASTROLE 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.

AZASTROLE 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, AZASTROLE may slow or stop the growth of cancer.

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why AZASTROLE has been prescribed for you.

Your doctor may have prescribed AZASTROLE for another reason.

AZASTROLE is only available with a doctor's prescription.

AZASTROLE is not addictive

Before you take AZASTROLE

When you must not take it

Do not take AZASTROLE if you are pregnant or intend to become pregnant.

AZASTROLE may affect your developing baby if you take it during pregnancy.

Do not breastfeed while taking AZASTROLE.

Your baby can take in AZASTROLE from breast milk if you are breastfeeding.

Do not take AZASTROLE if you have an allergy to:

- Anastrozole, the active ingredient of AZASTROLE.
- Any of the other ingredients of AZASTROLE listed at the end of this leaflet; or
- Other anti-oestrogen medicines.

Symptoms of an allergic reaction may include 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.

Do not take AZASTROLE if you are still having menstrual periods. AZASTROLE should only be taken by women who are no longer having menstrual periods.

Do not take AZASTROLE if you are a man.

Men are not normally treated with AZASTROLE.

Do not give AZASTROLE to a child.

AZASTROLE is not recommended for use in children.

Do not take AZASTROLE after the use by (expiry) date printed on the pack. Do not take AZASTROLE if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal

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

Tell your doctor if you have any allergies to the following:

- Any medicines; or
- Any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Liver problems;

- Kidney problems; or
- 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.

If you have not told your doctor about any of the above, tell him/her before you start taking AZASTROLE.

Taking other medicines

Tell your doctor or 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 should not be taken with AZASTROLE. 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; or
- Medicines from a class called "Luteinising Hormone Releasing Hormone (LHRH) agonists", such as goserelin or leuprorelin.

Talk to your doctor or pharmacist if you have any concerns or questions about taking AZASTROLE.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking this medicine.

How to take AZASTROLE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet every day.

When to take it

Take AZASTROLE at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Swallow AZASTROLE tablets whole, with a glass of water.

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

How long to take it

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

AZASTROLE helps to control your condition, but does not cure it. Therefore you must take AZASTROLE every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

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 double the 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 when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much AZASTROLE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking AZASTROLE

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 AZASTROLE.

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

If you go into hospital, please let the medical staff know that you are taking AZASTROLE.

Things you must not do

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

Do not take AZASTROLE to treat any other complaints unless your doctor tells you to.

Do not stop taking AZASTROLE unless you have discussed it with your doctor

Things to be careful of

Be careful driving or operating machinery until you know how AZASTROLE affects you.

Some patients may occasionally feel weak or sleepy.

Side effects

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

AZASTROLE helps most postmenopausal women with breast 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. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects.

If you get any side effects do not stop taking AZASTROLE without first talking to your doctor or pharmacist.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- **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; or**
- **Liver pain or swelling and/or a general feeling of unwell with or without jaundice (yellowing of the skin and eyes).**

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are uncommon or rare.

Tell your doctor if you notice any of the following and they worry you:

- Hot flushes;
- Feeling weak or a lack of energy;
- Feeling sleepy;
- Joint pain or stiffness;
- Vaginal dryness;
- Vaginal bleeding;
- Thinning of hair (hair loss);
- Mild skin rash;
- Feeling sick (nausea);
- Diarrhoea;
- Headache;
- Loss of appetite (anorexia);
- Vomiting; or
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of hand).

AZASTROLE 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 unwanted side effects.

These are the more common side effects of AZASTROLE. Mostly these are mild to moderate in nature.

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 may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using AZASTROLE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack it will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 30°C.

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

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Do not leave it on a window-sill or in the car on hot days.

Heat and dampness can destroy some 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.

Product description

What AZASTROLE looks like:

AZASTROLE 1 mg film-coated tablets are white to off-white round, film-coated, biconvex tablets, engraved with "A 1" on one face and plain on the other.

AZASTROLE tablets come in blister packs of 30 tablets

Ingredients:

Each tablet contains 1 mg of the active ingredient, anastrozole. Each tablet also contains the following ingredients:

- hypromellose
- lactose

- macrogol 400
- magnesium stearate
- povidone
- sodium starch glycollate
- titanium dioxide

Distributor

**ERIS Pharmaceuticals (Australia)
Pty Ltd**

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