

ARIMIDEX[®] TABLET 1MG

Anastrozole 1mg

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What Arimidex is used for

Arimidex is used to treat breast cancer in post-menopausal women.

How Arimidex works

Arimidex belongs to a group of medicines called aromatase inhibitors. This means that it interferes with some of the actions of aromatase, an enzyme within the body which effects the level of certain female sex hormones such as oestrogens.

Before you use Arimidex

- When you must not use it

Do not take Arimidex

- if you are pregnant or breast feeding your baby.
- if you are allergic to anastrozole or any of the other ingredients of Arimidex listed at the end of this leaflet

- Before you start to use it

Take special care with Arimidex

- if you are suffering from any disorder or disease which affects your heart, liver or kidneys. Please inform your doctor.

Arimidex is not recommended if you are pre-menopausal, and it should not be given to children.

- Taking other medicines

Please inform your doctor:

- if you take tamoxifen or medicine containing oestrogen (female sex hormone). It may lessen the effect of Arimidex.
- if you are taking or have recently taken any other medicines, even those not prescribed.

Please note that these statements may also apply to medicine used some time ago.

How to use Arimidex

- How much to use and when to use it

- Follow your doctor's instructions about when and how to take your tablets.
- The usual dose is one tablet taken daily.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.

- How long to use it

Take Arimidex as directed by your Healthcare provider. Do not stop taking your dose without talking to your Healthcare provider.

- If you forget to use it

Take the last missed dose as soon as you remember, as long as it is at least 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.

- If you use too much (overdose)

If you take more than your normal dose contact your doctor or nearest hospital.

While you are using it

- Things you must do

It is important to keep taking Arimidex every day and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said. Try to take the tablets at the

same time each day.

- Things you must not do

Do not stop taking your dose without talking to your Healthcare provider.

If you forget to take a dose, take the last missed dose as soon as you remember, as long as it is at least 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.

- Things to be careful of

Arimidex lowers the level of female hormones and this may lead to a loss of the mineral content of bones which might decrease their strength and as a possible consequence the risk of fractures may increase. This possible increased risk should be managed according to treatment guidelines for managing bone health in postmenopausal women. Women are encouraged to discuss this possible risk and treatment options with their physicians.

Pregnancy

Arimidex must not be used if you are pregnant.

Breast-feeding

Arimidex must not be used if you are breast-feeding.

Driving and using machines

Your tablets are unlikely to adversely affect your ability to drive a car or to operate machinery. However, some patients may occasionally feel weak or sleepy. If this happens to you, ask your doctor for advice.

Side effects

Like all medicines, Arimidex can have side effects.

Contact your doctor promptly if the following happens to you, as you may need further examinations or treatment:

- Extremely severe skin reactions (Stevens-Johnson syndrome)

with lesions, ulcers or blisters. This type of skin reaction is very rare.

- Allergic reaction with swelling of the face, lips, tongue and/or throat (angioedema) which may cause difficulty in swallowing and/or breathing.
- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), liver pain or liver swelling.

Tell your doctor if any of the following side-effects bother you:

- hot flushes
- feeling weak
- joint pain or joint stiffness
- inflammation of the joints (arthritis)
- bone loss (osteoporosis)
- carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand)
- vaginal dryness
- thinning of the hair (hair loss)
- nausea
- diarrhoea
- headache
- vaginal bleeding (usually in the first few weeks of treatment)
- anorexia (loss of appetite)
- vomiting
- sleepiness
- depression
- tickling, tingling or numbness of skin, loss/lack of taste
- rash, including inflammation of small blood vessels in the skin leading to skin rash
- trigger finger (a condition in which one of your fingers or your thumb catches in a bent position)
- Bone pain
- allergic reactions, such as hives or nettle-rash
- Muscle pain
- Increased calcium with or without the increase of parathyroid hormone in the blood. If you experience nausea, vomiting and thirst, you should tell your doctor. These symptoms may indicate

possible increased blood calcium levels. Your doctor may have to do certain blood tests to determine if there is increased calcium in your blood occurring with or without an increase of parathyroid hormone, a hormone that regulates calcium

An increased level of cholesterol (a type of fat in your blood) could also be seen with Arimidex.

Changes in blood tests of liver function could also be seen with Arimidex.

In a large clinical trial, a small increase in heart disease caused by reduced blood flow in the vessels of the heart was seen (ischaemic heart disease). This condition may present itself as chest pain.

Do not be alarmed by this list of possible events. You may not have any of them. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Arimidex

- Storage

- Do not store above 30°C.
- Keep your tablets in the carton they came in.

- Disposal

- If your doctor decides to stop your treatment dispose of your tablets in an appropriate way.
- Do not take your tablets after the expiry date on the container. Dispose of them in an appropriate way.
- Keep your tablets in a safe place where children cannot see or reach them. Your tablets

could harm them.

- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Arimidex is presented as white, biconvex, film-coated tablets containing 1 mg of anastrozole. A logo is impressed on one side and a tablet strength marking on the other side.

Arimidex tablets come in blister packs containing 28 tablets in strips of 14 tablets.

- Ingredients

- Active ingredient(s)

The active substance is anastrozole.

- Inactive ingredients

The other ingredients are lactose monohydrate, povidone, sodium starch glycolate, magnesium stearate, hypromellose, macrogol 300 and titanium dioxide.

- MAL number:

MAL19987960ARZ

Manufacturer

AstraZeneca Pharmaceuticals LP
Newark, Delaware,
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Product Registration Holder

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