

Arimidex[®]

Anastrozole 1 mg Tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Arimidex**. It does not contain all the information that is known about **Arimidex**. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Arimidex** 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 the medicine. You may need to read it again.

What Arimidex is used for

Arimidex is used to treat breast cancer in women after the change of life (menopause). **Arimidex** does not kill cancer cells. Rather, it stops or slows their growth.

Arimidex 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, **Arimidex** may slow or stop the growth of the cancer.

Arimidex is not addictive.

Arimidex is only available with a doctor's prescription.

Before you use Arimidex

When you must not use it

Do not use **Arimidex** if you have not yet experienced menopause or if you are a child. We do not know if **Arimidex** is safe for these patients.

Do not take Arimidex if you are a man. Men are not normally treated with **Arimidex**.

Do not use Arimidex if you are pregnant or breastfeeding your baby.

Do not take Arimidex if you have an allergy to:

- Anastrozole, the active ingredient of **Arimidex**
- Any of the other ingredients of **Arimidex** listed at the end of this leaflet
- 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 use **Arimidex** after the expiry date. This date is printed on the pack. It may have no effect at all or an unexpected effect if you take it after the expiry date. If the packaging of **Arimidex** appears torn or "tampered with" when you receive it, do not use the tablets.

These tablets are only for you and must not be given to anyone else. Do not use Arimidex to treat any other complaints unless your doctor tells you to.

Before you start to use it:

You must tell your doctor if:

1. You have allergies to:

- **Arimidex** (if you have taken this medicine previously and experienced an allergic reaction)
- any of the ingredients listed at the end of this leaflet or
- any other medicines or other substances, such as foods, preservatives or dyes.

2. You have the following medical conditions:

- any disease or disorder which affects your heart, kidney or liver
- 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 any of these conditions it may not be appropriate for you to take **Arimidex**.

Arimidex may cause inflammation in tendons. At any sign of tendon pain or swelling, rest the painful area and contact your doctor.

3. You are taking any of the following medicines:

- tamoxifen, a medicine used to treat breast cancer
- medicines which contain oestrogen such as medicines used in Hormone Replacement Therapy (HRT) or oral contraceptives
- medicines from a class called Luteinising Hormone Releasing Hormone (LHRH) agonists, such as goserelin or leuprorelin
- any health food products that contain natural oestrogens used for post-menopausal symptoms
- any other medicines, including medicines that you buy without a prescription at the chemist, supermarket or health food shop.

These other medicines may have some effect on the way **Arimidex** works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor any of the things above, please tell him/her before you start taking **Arimidex**.

Using Arimidex

How To Take Arimidex

Your doctor will have decided how much **Arimidex** you should take each day. The usual adult dose is one tablet taken daily. Try to take your tablets at the same time each day.

Arimidex tablets may be taken before or after food. **Arimidex** tablets should be swallowed whole with a drink of water. Do not chew the tablets.

Do not stop taking your tablets even if you are feeling well, until your doctor tells you.

How long to take it

Continue taking **Arimidex** for as long as your doctor or pharmacist tells you. **Arimidex** helps to control your condition, but does not cure it. Therefore you must take **Arimidex** 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.

Overdose

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre at 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much **Arimidex**, even if there are no signs of discomfort or poisoning.

While you are using Arimidex

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

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

Your doctor will tell you for how long you may need to take **Arimidex**. Only stop taking your tablets if your doctor tells you.

Things you must not do

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

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

Do not stop taking **Arimidex** unless you have discussed it with your doctor.

Things to be careful of

It is unlikely that **Arimidex** will affect your ability to drive a car or to operate machinery. However, some patients may occasionally feel weak or sleepy, and caution should be observed when driving or operating machinery while such symptoms persist. If this happens to you, ask your doctor for advice.

Side effects

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

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 for some side effects.

If you think you may have a side effect do not stop taking Arimidex without first talking to your doctor or pharmacist. Ask your doctor or pharmacist to answer any questions you may have about your treatment or this medicine.

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

- hot flushes
- feeling weak or lack of energy
- sleepiness
- joint pain or joint stiffness
- bone loss (osteoporosis)
- inflammation of the joints (arthritis)
- vaginal dryness
- vaginal bleeding (usually in the first few weeks of treatment)
- thinning of the hair (hair loss)
- skin rash, including inflammation of small blood vessels in the skin leading to skin rash
- nausea
- vomiting
- diarrhoea
- headache
- depression
- tickling, tingling or numbness of skin, loss/lack of taste
- anorexia (loss of appetite)

- allergic reactions, such as hives or nettle-rash
- carpal tunnel syndrome
- bone pain
- trigger finger (where your fingers or your thumb catches in a bent position)
- muscle pain
- increased calcium with or without 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.

Occasionally, some people taking **Arimidex** have had slight increases in cholesterol (blood fat). Some breast cancer patients may experience changes in their liver.

Cases of inflammation of a tendon (connective tissues that connect muscles to bones), or tendonitis have been observed during the use of similar class of medicines, which might also occur during treatment with **Arimidex**.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Arimidex**.

After using Arimidex

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or blister pack they may not keep well. Keep in a cool, dry place. Do not store above 30°C.

Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them. A locked cupboard at least one and a half metres above the ground is a good place to store 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 it looks like:

Arimidex comes in white tablets. One side of the tablet is marked with a logo consisting of the letter 'A' with an arrowhead attached to the foot of the extended right leg of the 'A'. The other side is impressed with a tablet strength marking ('Adx 1').

Arimidex comes in blister packs of 30 tablets.

Ingredients:

Each tablet contains 1 mg of the active ingredient anastrozole. Each tablet also contains inactive substances which are commonly used in the manufacture of medicines. These are:

- lactose
- povidone
- sodium starch glycollate
- magnesium stearate
- hypromellose

- macrogol 300
- titanium dioxide

Marketed by:

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