

PACKAGE LEAFLET: INFORMATION FOR THE USER

Arimidex® 1mg Film-coated Tablets (anastrozole)

Your medicine is available using the name Arimidex 1mg Film-Coated Tablets but will be referred to as Arimidex throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Arimidex is and what it is used for
2. What you need to know before you take Arimidex
3. How to take Arimidex
4. Possible side effects
5. How to store Arimidex
6. Contents of the pack and other information

1. What Arimidex is and what it is used for

Arimidex contains a substance called anastrozole. This belongs to a group of medicines called 'aromatase inhibitors'. Arimidex is used to treat breast cancer in women who have gone through the menopause.

Arimidex works by cutting down the amount of the hormone called estrogen that your body makes. It does this by blocking a natural substance (an enzyme) in your body called 'aromatase'.

2. What you need to know before you take Arimidex

Do not take Arimidex

- if you are allergic to anastrozole or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding (see the section called 'Pregnancy and breast-feeding').

Do not take Arimidex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Arimidex.

Warnings and precautions

Talk to your doctor, or pharmacist or nurse before taking Arimidex

- if you still have menstrual periods and have not yet gone through the menopause.
- if you are taking a medicine that contains tamoxifen or medicines that contain estrogen (see the section called 'Other medicines and Arimidex').
- if you have ever had a condition that affects the strength of your bones (osteoporosis).
- if you have problems with your liver or kidneys.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Arimidex.

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

Other medicines and Arimidex

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Arimidex can affect the way some medicines work and some medicines can have an effect on Arimidex.

Do not take Arimidex if you are already taking any of the following medicines:

- Certain medicines used to treat breast cancer (selective estrogen receptor modulators), e.g. medicines that contain tamoxifen. This is because these medicines may stop Arimidex from working properly.
- Medicines that contain estrogen, such as hormone replacement therapy (HRT).

If this applies to you, ask your doctor or pharmacist for advice.

Tell your doctor or pharmacist if you are taking the following:

- A medicine known as an 'LHRH analogue'. This includes gonadorelin, buserelin, goserelin, leuprorelin and triptorelin. These medicines are used to treat breast cancer, certain female health (gynaecological) conditions, and infertility.

Pregnancy and breast-feeding

Do not take Arimidex if you are pregnant or breast-feeding. Stop Arimidex if you become pregnant and talk to your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Arimidex is not likely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel weak or sleepy while taking Arimidex. If this happens to you, ask your doctor or pharmacist for advice.

Arimidex contains lactose

Arimidex contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Arimidex

Always take Arimidex exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is one tablet once a day.
- Try to take your tablet at the same time each day.
- Swallow the tablet whole with a drink of water.
- It does not matter if you take Arimidex before, with or after food.

Keep taking Arimidex for as long as your doctor or pharmacist tells you to. It is a long-term treatment and you may need to take it for several years. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents

Arimidex should not be given to children and adolescents.

If you take more Arimidex than you should

If you take more Arimidex than you should, talk to a doctor straight away.

If you forget to take Arimidex

If you forget to take a dose, just take your next dose as normal. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Arimidex

Do not stop taking your tablets unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (affect more than 1 in 10 people)

- Headache.
- Hot flushes.
- Feeling sick (nausea).
- Skin rash.
- Pain or stiffness in your joints.
- Inflammation of the joints (arthritis).
- Feeling weak.
- Bone loss (osteoporosis).

Common side effects (affect 1 to 10 people in 100)

- Loss of appetite.
- Raised or high levels of fatty substance known as cholesterol in your blood. This would be seen in a blood test.
- Feeling sleepy.
- Carpal tunnel syndrome (tingling, pain, coldness, weakness in parts of the hand).
- Tickling, tingling or numbness of skin, loss/lack of taste.
- Diarrhoea.
- Being sick (vomiting).
- Changes in blood tests that show how well your liver is working.
- Thinning of your hair (hair loss).
- Allergic (hypersensitivity) reactions including face, lips, or tongue.
- Bone pain.
- Vaginal dryness.
- Bleeding from the vagina (usually in the first few weeks of treatment - if the bleeding continues, talk to your doctor).
- Muscle pain.

Uncommon side effects (affect 1 to 10 people in 1,000)

- Changes in special blood tests that show how your liver is working (gamma-GT and bilirubin).
- Inflammation of the liver (hepatitis).
- Hives or nettle rash.
- Trigger finger (a condition in which your finger or thumb catches in a bent position).
- Increased amounts of calcium in your blood. If you experience nausea, vomiting and thirst, you should tell your doctor, or pharmacist or nurse as you may need to have blood tests.

Rare side effects (affect 1 to 10 people in 10,000)

- Rare inflammation of your skin that may include red patches or blisters.
- Skin rash caused by hypersensitivity (this can be from allergic or anaphylactoid reaction).
- Inflammation of the small blood vessels causing red or purple colouring of the skin. Very rarely symptoms of joint, stomach, and kidney pain may occur; this is known as 'Henoch-Schönlein purpura'.

Very rare side effects (affect less than 1 person in 10,000 people)

- An extremely severe skin reaction with ulcers or blisters on the skin. This is known as 'Stevens-Johnson syndrome'.
- Allergic (hypersensitivity) reactions with swelling of the throat that may cause difficulty in swallowing or breathing. This is known as 'angioedema'.

If any of these happen to you, call an ambulance or see a doctor straight away – you may need urgent medical treatment.

Effects on your bones

Arimidex lowers the amount of the hormone called estrogen that is in your body. This may lower the mineral content of your bones. Your bones may be less strong and may be more likely to fracture. Your doctor will manage these risks according to treatment guidelines for managing bone health in women who have gone through the menopause. You should talk to your doctor about the risks and treatment options.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arimidex

- Keep out of the sight and reach of children.
- Keep your tablets in the container they came in.
- Do not use Arimidex after the expiry date (EXP) which is stated on the carton and the blister. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- 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.
- If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

6. Contents of the pack and other information

What Arimidex contains

- The active substance is anastrozole. Each tablet contains 1 milligram (mg) of anastrozole.
- The other ingredients are lactose monohydrate, macrogol, magnesium stearate, hypromellose, povidone, sodium starch glycolate and titanium dioxide.

What Arimidex looks like and contents of the pack

Arimidex comes as film-coated tablets. The tablets are white, round and marked with a logo on one side and a tablet strength marking on the other side.

Arimidex comes in blister packs of 28 tablets.

Manufacturer

Manufactured by: AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/161/1

Leaflet issue and revision date (ref): 20.10.14

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This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, UK	Arimidex
Slovenia	Arimidex 1mg filmsko obložene tablete