

Package Leaflet: Information for the User
Arimidex® 1 mg film-coated tablets
(anastrozole)

Your medicine is known by the above name, 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 and as a preventative treatment in postmenopausal women at moderate or high risk of breast cancer.

Arimidex® works by cutting down the amount of the hormone called oestrogen 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).
- 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 oestrogen (see the section called 'Other medicines and Arimidex®').
- if you have, or have ever had a condition that affects the strength of your bones (osteoporosis or osteopenia). Arimidex® lowers the levels of female hormones and this may lead to a loss of the mineral content of bones, which might decrease their strength. You may have to have bone density tests during treatment. Your doctor can give you medicine to prevent or treat the bone loss. Women with severe osteoporosis are not suitable for anastrozole treatment.
- if you have problems with your liver or kidneys.
- if you have heart problems or have had a stroke.

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, have recently taken or might take 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 oestrogen receptor modulators), e.g. medicines that contain tamoxifen. This is because these medicines may stop Arimidex® from working properly.
- Medicines that contain oestrogen, 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.

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 medicinal product.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. HOW TO TAKE ARIMIDEX®

Always take this medicine 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.

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

Stop taking Arimidex® and seek urgent medical treatment, if you experience any of the following serious side effects:

Common (may affect up to 1 in 10 people):

- Allergic (hypersensitivity) reactions including face, lips, or tongue.

Rare (may affect up to 1 in 1,000 people):

- Rare inflammation of your skin that may include red patches or blisters (erythema multiforme).

Very rare (may affect up to 1 in 10,000 people):

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

Other side effects

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)
- Depression.

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)
- 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)

- 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'.

Side effects with frequency not known (frequency cannot be estimated from the available data)

- Dry eye
- Lichenoid eruption (small, red or purple itchy bumps on the skin)
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)
- Rupture of a tendon (connective tissues that connect muscles to bones)
- Memory impairment

Effects on your bones

Arimidex® lowers the amount of the hormone called oestrogen 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.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. 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.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Arimidex® contains

- The active substance is anastrozole. Each film-coated tablet contains 1 mg of anastrozole.
- The other ingredients are: lactose monohydrate, povidone (K29-32), sodium carboxymethyl starch, magnesium stearate, hypromellose, macrogol 300, titanium dioxide.

What Arimidex® looks like and contents of the pack

White, round, biconvex film-coated tablets of about 6.1 mm marked 'A' on one side and 'Adx1' on the other side. Arimidex® comes in blister packs of 28 tablets.

Manufactured by Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, Muenster Nordrhein-Westfalen, 48 159, Germany.

AstraZeneca AB, Gartunavagen, SE-151 85 Sodertalje, Sweden.

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

AstraZeneca GmbH, Tinsdaler Weg 183, D-22880 Wedel, Germany.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU, UK.

Revision date: 04.08.2025

PL 16378/1204

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Is this leaflet hard to see or read?
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Tel: 020 8896 9054 for help.
Ref. number: 1204/V3**