

PACKAGE LEAFLET: INFORMATION FOR THE USER
Anastrozole 1 mg Film-coated Tablets
Anastrozole

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET:

- 1. What Anastrozole is and what it is used for**
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1. WHAT ANASTROZOLE IS AND WHAT IT IS USED FOR

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

Do NOT take Anastrozole

- If you are allergic (hypersensitive) to anastrozole or any of the other ingredients of Anastrozole (listed in section 6)
- If you are pregnant or breast-feeding (see the section called 'Pregnancy and breast-feeding')

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Anastrozole

- 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 Anastrozole').
- 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 Anastrozole.

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

Other medicines and Anastrozole

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 Anastrozole can affect the way some medicines work and some medicines can have an effect on Anastrozole.

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

Driving and using machines

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

Anastrozole contains lactose

Anastrozole 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 ANASTROZOLE

Always take Anastrozole 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 Anastrozole before, with or after food.

Keep taking Anastrozole for as long as your doctor tells you to. It is a long-term treatment and you may need to take it for several years.

Use in children and adolescents

Anastrozole should not be given to children and adolescents.

If you take more Anastrozole than you should

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

If you forget to take Anastrozole

If you forget to take a dose, just take your next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Anastrozole

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

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

4. POSSIBLE SIDE EFFECTS

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

Very common side effects (may 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 (may affect up to 1 in 10 people):

- Loss of appetite.
- Raised or high levels of a 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).
- 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 involving the 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 (may affect up to 1 in 100 people):

- 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 as you may need to have blood tests.

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

- 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 (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'.
- 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

Anastrozole 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 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 ANASTROZOLE

Keep this medicine out of the sight and reach of children.

Do not use Anastrozole after the expiry date which is stated on the outer packaging after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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.

6. FURTHER INFORMATION

What Anastrozole contains

- The active ingredient is anastrozole. Each film-coated tablet contains 1 mg anastrozole.
- The other ingredients are: Tablet core: lactose monohydrate, magnesium stearate (E572), povidone K-30, sodium starch glycolate type A; Film-coating: hypromellose (E464), macrogol 400 and 6000 and titanium dioxide (E171).

What Anastrozole looks like and contents of the pack

Anastrozole 1 mg Film-coated Tablets are white to off-white, round tablets. One side of the tablet is marked with the number "93" and the other side with "A10".

Anastrozole 1 mg Film-coated Tablets are available in packs of 28 tablets.

Product procured from within the EU by the Parallel Product Authorisation Holder:

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

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Manufacturer

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