

Package leaflet: Information for the users

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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Anastrozole Tablets are and what they are used for

Anastrozole Tablets contain a substance called anastrozole. This belongs to a group of medicines called aromatase inhibitors. It is used to treat breast cancer in women who have gone through the menopause.

Anastrozole Tablets work 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 Anastrozole Tablets

Do not take Anastrozole Tablets:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Anastrozole Tablets:

- 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 Anastrozole Tablets’).
- if you have or ever had a condition that affects the strength of your bones (osteoporosis). Anastrozole 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.
- 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 Tablets.

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

Children and adolescents

Do not give this medicine to children because it is unlikely to be safe.

Other medicines and Anastrozole Tablets

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 estrogen receptor modulators), e.g., medicines that contain tamoxifen. This is because these medicines may stop Anastrozole 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 Anastrozole Tablets if you are pregnant or breast-feeding. Stop anastrozole if you become pregnant and talk to your doctor.

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

Driving and using machines

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

Anastrozole Tablets contain lactose

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

Anastrozole Tablets contain Sodium

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

3. How to take Anastrozole Tablets

Always take Anastrozole Tablets 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.
- Swallow the tablet whole with a drink of water.
- Try to take your tablet at the same time each day.

It does not matter if you take anastrozole before, with or after food.

Keep taking Anastrozole tablets 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

Anastrozole tablets should not be given to children and adolescents.

If you take more Anastrozole Tablets than you should

If you take more Anastrozole Tablets than you should, talk to a doctor straight away. If you have taken more Anastrozole Tablets than you were told to, or if someone else has taken any Anastrozole Tablets, contact the accident and emergency department of your nearest hospital. Take any leftover tablets or empty box with you for easier identification.

If you forget to take Anastrozole Tablets

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 Anastrozole Tablets

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.

Stop taking Anastrozole Tablets and seek urgent medical treatment, if you experience any of the following serious but very rare side effects:

- 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’.

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- Trigger finger (a condition in which your finger or thumb catches in a bent position)
- 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
- 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 (may affect up to 1 in 1000 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’.

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.

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

Website: www.hpra.ie.

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

5. How to store Anastrozole Tablets

- Keep out of the sight and reach of children. Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.
- No specific storage conditions recommended.
- Always return any leftover medicine to your pharmacist. Only keep it if your doctor tells you to.
- Do not use the Anastrozole Tablets after the expiry date, which is stated on the carton and blister after (EXP). The expiry date refers to the last day of that month.
- Keep your tablets in the container they came in.
- 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. Contents of the pack and other information

What Anastrozole Tablets contain:

The **active substance** is anastrozole. Each film-coated tablet contains 1mg of anastrozole.

The **other ingredient(s)** are:

Core tablet: Lactose Monohydrate(95.250 mg), Povidone K-30, Sodium starch glycolate (type A), Magnesium Stearate

Film-coating: Titanium dioxide (E171), Macrogol 300, Hypromellose E-5

What Anastrozole Tablets look like and contents of the pack:

Anastrozole Tablets are white to off white in colour, round, biconvex, film-coated tablets with ‘AHI’ debossing on one side and plain on other side.

Anastrozole Tablets are packed in blisters in pack of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 300 tablets.

Not all packs may be marketed.

Marketing Authorisation Holder:

Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomińska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

This medicine is authorized in the Member States of the European Economic Area under the following names:

Name of the Member State	Name of the medicine
Belgium	Anastrozole Accord Healthcare 1 mg Comprimés Pelliculés / Filmomhulde Tabletten / Filmtabletten
Denmark	Anastrozole Accord 1 mg filmovertrukne tabletter
Estonia	Anastrozole Accord 1 mg õhukese polümeerikattega tabletid
Italy	ANTABREST 1 mg compresse rivestite con film
Ireland	Anastrozole 1mg Film-coated Tablets
France	Anastrozole Accord 1 mg Comprimés Pelliculés
Cyprus	Αναστροζόλη Ακόρντ 1 mg, δισκία επικαλυμμένα με λεπτό υμένιο
Latvia	Anastrozole Accord 1 mg apvalkotās tabletes
Lithuania	Anastrozole Accord 1 mg plėvele dengtos tabletės
Malta	Anastrozole Accord 1 mg Film-coated Tablets
The Netherlands	Anastrozole Accord 1mg Filmomhulde Tabletten
Portugal	Anastrozol Accord 1 mg comprimidos revestidos por película
Romania	Anastrozole Medico Uno 1 mg comprimate filmate
Spain	Anastrozol Accord 1 mg comprimidos recubiertos con película EFG
Hungary	Anastrozole Accord 1 mg Filmtabletta
Germany	Anastrozole Accord 1 mg Filmtabletten
Sweden	Anastrozole Accord 1 mg filmdragerade tabletter

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