



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

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2. What you need to know before you take Anastrozole Tablets
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1. What Anastrozole Tablets is and what it is used for

Anastrozole Tablets are one of a group of medicines called aromatase inhibitors. This means that it interferes with some of the actions of aromatase, an enzyme within the body which affects the level of certain female sex hormones such as oestrogens. It is used to treat breast cancer in post-menopausal women.

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
- If you have not yet had the menopause
- If you are pregnant or breast-feeding
- If you have moderate or severe liver disease
- If you are taking medicines that contain oestrogen (see also "Other medicines and Anastrozole Tablets" below)
- If you are taking tamoxifen (see also "Other Medicines and Anastrozole Tablets", below).

Warnings and precautions

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

- Have osteoporosis or have had any condition that affects the strength of your bones. 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.
- Are unsure whether or not you have gone through menopause yet. Your doctor should check your hormone levels.
- Have ever had a condition that affects the strength of your bones (osteoporosis).
- Have problems with your liver or kidneys

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, including medicines obtained without a prescription. 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 any of these applies to you, ask your doctor or pharmacist for advice.

Tell your doctor if you are taking the following:

- Are taking LHRH analogues e.g. gonadorelin, buserelin, goserelin, leuprorelin and triptorelin. (medicines used to treat breast cancer, certain gynaecological problems or infertility). No studies have been done on the combination of LHRH analogues and anastrozole. Therefore, anastrozole and LHRH analogues should not be used in combination.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Anastrozole Tablets with food and drink:

There is no effect on absorption of Anastrozole Tablets when taken with meal.

Pregnancy and breast-feeding and fertility:

Do not take Anastrozole Tablets if you are pregnant or breast-feeding your babies. Stop taking anastrozole if you are pregnant and talk to your doctor.

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

Driving and using machines:

Anastrozole Tablets are unlikely to adversely affect your ability to drive a car or to operate machinery. However, some patient may occasionally feel weak or sleepy. If this happens to you, you should not drive or operate machinery and ask your doctor or pharmacist for advice.

Anastrozole Tablets contains lactose:

Anastrozole Tablets contains lactose (milk sugar) which is a type of sugar. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Anastrozole Tablets

Always take Anastrozole Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The recommended adult dose is one tablet taken daily.
- 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. Do not stop taking your tablets even if you are feeling well, unless your doctor tells you.

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 have taken more Anastrozole Tablets than you were told to, or if someone else has taken any Anastrozole Tablets, contact accident and emergency department of your nearest hospital. Take any left over tablets or empty box with you for easier identification.

If you forget to take Anastrozole Tablets:

Do not take double dose (two doses at the same time) to make up for a forgotten dose, just resume your usual schedule.

If you stop taking Anastrozole Tablets:

Do not stop taking your tablets even if you are feeling well, unless your doctor tells you. If you have any further question on the use of the product, ask your doctor or pharmacist.

4. Possible side effects

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

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

- Hot flushes.
- Feeling weak.
- Pain or stiffness in your joints.
- Inflammation of the joints (arthritis)
- Skin rash (this can include a type of rash called 'hives' or nettle rash).
- Feeling sick (nausea).
- Headache.
- Bone loss (osteoporosis).

Common (may affects up to 1 in 10 people)

- Vaginal dryness.
- Bleeding from 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 substances 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 affects 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)

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

For UK - You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

For Ireland - 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

5. How to store Anastrozole Tablets

- Keep out of the reach and sight 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 contains:

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 looks like and content 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 Limited,
Sage House,
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Manufacturer:

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