PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

1. WHAT ANASTROZOLE 1 MG ARE AND WHAT THEY ARE 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 and as a preventative treatment in postmenopausal women at moderate or high risk of breast cancer.

Anastrozole work 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 1 MG

Do not take Anastrozole 1 mg 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 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 or nurse 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 1 mg').
- if you have, or have ever had a condition that affects the strength of your **bones** (osteoporosis or osteopenia). 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. 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 Anastrozole 1 mg.

If you go into the hospital, let the medical staff know you are taking Anastrozole 1 mg.

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

Other medicines and Anastrozole 1 mg
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 1 mg 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.

Anastrozole 1mg with food and drink
There is no effect on absorption of Anastrozole 1mg when taken with a meal.

Pregnancy and breast-feeding
Do not take Anastrozole 1 mg if you are **pregnant or breast-feeding**. Stop Anastrozole 1 mg 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
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 1 mg contain lactose
Anastrozole 1 mg contain **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 ANASTROZOLE 1 MG

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 Anastrozole 1 mg before, with or after food.

Keep taking Anastrozole 1 mg 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 1 mg should not be given to children and adolescents.

If you take more Anastrozole 1 mg than you should
If you take more Anastrozole than you should, talk to a doctor straight away. If you have taken more Anastrozole 1mg than you were told to, or if someone else has taken any Anastrozole 1mg, 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 1 mg
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 1 mg
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 Anastrozole 1 mg 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'.

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Other side effects
Very common (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)
- Depression

Common (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)
- 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 (may affect upto 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 or nurse as you may need to have blood tests

Rare (may affect upto 1 in 1,000)
- 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.

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 Website: 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 ANASTROZOLE 1 MG

Keep this medicine 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.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the packaging after 'EXP'. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Anastrozole 1 mg contain
- The active substance is anastrozole. Each film-coated tablet contains 1 mg of anastrozole.
- The other ingredients in the tablet core are lactose monohydrate, sodium starch glycolate (type A), povidone (E1201), and magnesium stearate (E572).

The ingredients in the tablet coating are macrogol 400, hypromellose (E464), and titanium dioxide (E171).

What Anastrozole 1 mg looks like and content of the pack
White film-coated round biconvex tablet, with the inscriptions "ANA" and "1" on one side.

Anastrozole is available in blisters of 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 or 300 tablets and in hospital blisters of 28, 50, 84, 98, 300 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
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