

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

ANASTROZOLE TABLETS 1MG TAJ PHARMA

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. 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 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 The full name of the product is Anastrozole 1mg Film-coated Tablets but within the leaflet it will be referred to as Anastrozole tablets.

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'. Anastrozole tablets are 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 section 6).
- are pregnant or breast feeding (see the section called 'Pregnancy and breastfeeding').

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 or pharmacist 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 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 tablets.

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

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



Do not take Anastrozole tablets 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 tablets 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 taking Anastrozole tablets 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 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

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 TABLETS

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- The recommended dose is **one tablet** (1mg anastrozole) 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 tablets before, with or after food.

Keep taking Anastrozole tablets 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 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 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 or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Serious side effects:

If you get any of the following serious side effects, call an ambulance or see a doctor straight away - you may need urgent medical treatment.

 An extremely severe skin reaction with ulcers or blisters on the skin. This is known as 'Stevens-Johnson syndrome'.
 Very rare (may affect less than 1 person in 10,000 people);



 Allergic (hypersensitivity) reactions with swelling of the throat that may cause difficulty in swallowing or breathing. This is known as 'angioedema'. Very rare (may affect less than 1 person in 10,000 people);

Other side effects:

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

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

Common side effects (may affect 1 to 10 people in 100):

- 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 including 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)

Uncommon side effects (may affects 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)

Rare side effects (may affect 1 to 10 people in 10,000):

- 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 estrogen

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.

5. HOW TO STORE ANASTROZOLE TABLETS

Keep this medicine out of 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 carton and blister 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 FURTHER INFORMATION

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p.m. EST

What Anastrozole tablets contain

- The other ingredients in the tablet core are lactose monohydrate, sodium starch glycolate, povidone (E1201) and magnesium stearate (E572).
- The ingredients in the tablet coating are macrogol, hypromellose (E464) and titanium dioxide (E171).

What Anastrozole tablets look like and contents of the pack

Anastrozole is a white film-coated round tablet, Anastrozole is available in hospital blisters of 28 tablets.

7. MANUFACTURED IN INDIA BY:

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