

Anastrozole NORMON 1 mg film-coated tablets

Read this leaflet carefully before using the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any question, consult your doctor or pharmacist.
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.
- If you think any of the adverse effects you suffer are severe or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

This leaflet contains:

1. **What Anastrozole NORMON 1 mg film-coated tablets is and what it is used for**
2. **Before taking Anastrozole NORMON 1 mg film-coated tablets**
3. **How to take Anastrozole NORMON 1 mg film-coated tablets**
4. **Possible side effects**
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1. WHAT Anastrozole NORMON 1 mg film-coated tablets IS AND WHAT IT IS USED FOR

Anastrozole NORMON 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 estrogen that your body makes. It does this by blocking a natural substance (an enzyme) in your body called 'aromatase'.

2. BEFORE TAKING Anastrozole NORMON 1 mg film-coated tablets

Do not take Anastrozole NORMON:

- if you are allergic (hypersensitive) to anastrozole or any of the other ingredients of Anastrozole NORMON (listed in section 6: Further information).
- 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.

Take special care with Anastrozole NORMON

Talk to your doctor or pharmacist before taking Anastrozole NORMON.

- 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').
- 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.

Use of other drugs

Tell your doctor or pharmacist if you are taking or have recently taken 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 breastfeeding

Do not take anastrozole 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 the use of machinery

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.

Important information about some of the components of Anastrozole NORMON

Anastrozole tablets contain lactose, which is a type of sugar. If your doctor has said that you suffer from intolerance to certain sugars, ask before taking this medicine.

Athletes are informed that this drug contains a component that could give positive results in a drug test.

3. HOW TO TAKE Anastrozole NORMON 1 mg film-coated tablets

Follow the instructions for the administration of Anastrozole NORMON exactly as your doctor tells you. Ask your doctor or pharmacist if you have any doubts.

- The normal 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

Anastrozole tablets should not be given to children and adolescents.

If you take more Anastrozole NORMON than you should:

If you have taken more anastrozole than you should, talk to a doctor straight away.

If you forget to take Anastrozole NORMON:

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 treatment with Anastrozole NORMON

Do not stop taking your tablets unless told to do so by your doctor.

If you have any other doubts about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS.

Like all medicines, Anastrozole NORMON 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 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 affect 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’.

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 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.

If you think any of the side effects you suffer are severe or if you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE Anastrozole NORMON 1 mg film-coated tablets

Keep out of the reach and sight of children.

Store below 30°C and protect from humidity.

Do not use Anastrozole NORMON after the expiry date shown on the packaging after “Exp”. Expiry date is the last day of the month indicated.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of medicinal products you do not need. This will help protect the environment.

6. FURTHER INFORMATION

Composition of Anastrozole NORMON

The drug substance is anastrozole. Each tablet contains 1 mg of anastrozole.

The other components (excipients) are:

Core of the tablet: lactose monohydrate (lactose), povidone (E-1201), sodium starch glycolate (of potato gluten-free) and magnesium stearate (E-572).

Components (excipients) of the film coating of the tablet: hypromellose (E-464), macrogol 6000, titanium dioxide (E-171) and talc.

Anastrozole NORMON appearance and contents of the package

Anastrozole NORMON is presented in the form of film coated tablets. The tablets are white or almost white, round and biconvex,

Each package contains 28 film-coated tablets.

Marketing authorisation holder and manufacturer:

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 - 28760 -Tres Cantos - Madrid (SPAIN).

This leaflet was last revised in January 2016