

Letrozole NORMON 2.5 mg film-coated tablets

Read all of this leaflet carefully before using this 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 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 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.

This leaflet contains:

1. What Letrozole NORMON is and when it is used for
2. Before taking Letrozole NORMON
3. How to take Letrozole NORMON
4. Possible side effects
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1. What Letrozole NORMON is and when it is used for

• What Letrozole NORMON is

Letrozole NORMON contains an active substance called letrozole. It belongs to a group of medicines called aromatase inhibitors. It is a hormonal (or "endocrine") breast cancer treatment.

• What Letrozole NORMON are used for

Letrozole is used to prevent breast cancer from happening again. It can be used as first treatment after breast surgery or following five years of treatment with tamoxifen. Letrozole is also used to prevent breast tumour spreading to other parts of the body in patients with an advanced disease.

Letrozole NORMON should only be used in case of oestrogen-receptor positive breast cancer and only in women who have gone through the menopause (the end of menstrual periods).

• How Letrozole NORMON works

The growth of breast cancer is normally stimulated by oestrogens, which are female sex hormones. Letrozole reduces the amount of oestrogen by blocking an enzyme ("aromatase") involved in the production of oestrogens. As a consequence tumour cells grow slow or stop growing and/or spreading to other parts of the body.

• Control of treatment with Letrozole NORMON

Letrozole should only be taken under strict medical control. Your doctor will regularly control your situation to check that the treatment is having the desired effect. Letrozole can produce a decrease in bone thickness or loss of bone (osteoporosis) due to the reduction in oestrogens in the body. Your doctor may decide to measure your bone density before, during and after treatment.

If you have any questions on how Letrozole NORMON acts or why it has been prescribed to you, consult your doctor.

2. Before taking Letrozole NORMON

Follow all the doctor's instructions carefully. These may differ from the general information in this leaflet.

• Do not take Letrozole NORMON:

- If you are allergic (hypersensitive) to letrozole or to any of the components of Letrozole NORMON listed in Section 6 of this leaflet.
- If you still have menstrual cycles, i.e. you have not yet gone through the menopause.
- If you are pregnant.
- If you are breast-feeding.

If any of these conditions apply to you, **tell your doctor before taking Letrozole NORMON.**

• Take special care with Letrozole NORMON

- If you are suffering from severe kidney disease.
- If you are suffering from severe liver disease.
- If you have a history of osteoporosis or bone fractures (see also Section 1 "Control of treatment with Letrozole NORMON").

If any of these conditions apply to you, **tell your doctor.** Your doctor will take this into account during your treatment with Letrozole NORMON.

• Use of other medicines

Tell your doctor or pharmacist if you are using or have recently used any other medicines, even those obtained without a prescription.

• Children and adolescents (under 18 years of age)

Letrozole NORMON is not used in children and adolescents.

• Elderly patients (over 65 years of age)

Letrozole NORMON can be used by people over 65 years of age at the same dose as for other adults.

• Pregnancy and breast-feeding

Do not take Letrozole NORMON if you are pregnant or breast-feeding, as it may harm your baby. If you are pregnant or breast-feeding, tell your doctor before taking Letrozole NORMON. However, as letrozole is only recommended in post-menopausal women, the restrictions for pregnancy and breastfeeding will probably not affect you.

• Driving and the using machines

If you feel dizzy, tired, and drowsy or do not feel well, do not drive or handle tools or machines until you feel better.

• Important information for athletes

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

• Important information about some of the ingredients of Letrozole NORMON:

Letrozole contains lactose (milk sugar). If your doctor has indicated that you suffer from intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to take Letrozole NORMON

Follow the instructions for the administration of Letrozole NORMON exactly as your doctor tells you. Check with your doctor or pharmacist if you are not sure.

• What amount of Letrozole NORMON you should take

The usual dose is one tablet of Letrozole NORMON is to be taken once a day. If you take Letrozole NORMON at the same time each day, it will help you remember when to take your tablet.

• How to take Letrozole NORMON

You should take the whole tablet with a glass of water or other liquid.

• How long you should take Letrozole NORMON for

Continue taking Letrozole NORMON every day for as long as your doctor tells you. You may need to take it for months or even years. If you have any questions about how long to keep taking Letrozole NORMON, talk to your doctor.

• If you take more Letrozole NORMON than you should

If you have taken more Letrozole NORMON tablets than you should, or if another person has accidentally taken the tablets, contact your doctor or pharmacist at once or go to the nearest hospital indicating the medicine and the amount taken. Show them the pack of tablets. You may require medical treatment.

• If you forget to take Letrozole NORMON:

- If it is almost time for your next tablet (e.g. within 2 or 3 hours), do not take the forgotten dose and take the next dose at the scheduled time.
- Otherwise, take the dose as soon as you remember, and then take the next tablet as you would normally.
- Do not take a double dose to make up for the forgotten dose.

• **If you stop treatment with Letrozole NORMON:**

Do not stop taking Letrozole NORMON unless your doctor tells you. See also the section "How long to take Letrozole NORMON"

4. Possible side effects

Like all medicines, Letrozole NORMON can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear after a few days or weeks of treatment. Some of them, such as hot flushes, hair loss or vaginal bleeding may be due to the lack of oestrogens. Do not be alarmed by this list of possible side effects. You might not experience any of them.

Some side effects could be serious: *These side effects may be rare or uncommon, i.e., they may affect 1 to 100 in every 10,000 patients*

- If you notice weakness, paralysis or loss of feeling in an arm or leg or any other part of the body, loss of coordination, nausea, or difficulty speaking or breathing (sign of brain disorder, e.g. stroke).
- Sudden, oppressive chest pain (sign of heart disorder).
- If you notice difficulty breathing, chest pain, fainting, fast heart rate, bluish skin discoloration, or sudden pain in the arm or leg (foot) (signs that a blood clot has formed).
- If you notice swelling or redness along a vein that is extremely soft or possibly painful when touched.
- If you have high fever, chills or mouth ulcers due to infections (lack of white blood cells).
- If you suffer from severe or continuous blurred vision.

Inform your doctor immediately.

Some side effects are very common: *These side effects may affect more than 10 in every 100 patients.*

- Hot flushes.
 - Fatigue.
 - Increased sweating.
 - Pain in the bones or joints (arthralgia).
- If any of these affects you severely, tell your doctor.

Some side effects are common: *These side effects may affect from 1 to 10 in every 100 patients.*

- Skin Rash.
 - Headache.
 - Dizziness.
 - General feeling unwell.
 - Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea.
 - Increase or decrease in appetite.
 - Muscle pain.
 - Thinning or wasting of bones (osteoporosis), which causes bone fractures in some cases (see also "Control of treatment with Letrozole NORMON").
 - Swelling of the arms, hands, feet or ankles (oedema).
 - Depression.
 - Weight increase.
 - Hair loss.
- If any of these affects you severely, tell your doctor.

Some side effects are uncommon: *These side effects may affect from 1 to 10 in every 1,000 patients.*

- Nervous disorders such as anxiety, nervousness, irritability, , memory problems, somnolence, insomnia.
- Problems of sensitivity, especially touch.
- Eye disorders, such as blurred vision, eye irritation.
- Palpitations, rapid heart rate, increase in blood pressure (hypertension).
- Skin disorders such as itching (urticaria) or dry skin.
- Vaginal disorders such as bleeding, discharges or dryness.
- Abdominal pain.
- Rigidity of the joints (arthritis).
- Breast pain.
- Fever.
- Thirst, taste disorders, dry mouth.
- Dryness of the mucous membranes.
- Weight decrease.
- Urinary tract infection, increased frequency of urination.
- Cough.

If any of these affects you severely, tell your doctor.

You may also experience alterations on blood tests while taking Letrozole NORMON, such as high cholesterol levels (hypercholesterolemia) or increased liver enzyme levels.

If you notice any side effects not listed in this leaflet or suffer any of the described side effects, tell your doctor or pharmacist.

5. Storage of Letrozole NORMON

Keep out of the reach and sight of children.

Do not use Letrozole NORMON after the expiry date shown on the packaging. Expired date is the last day of the month indicated.

Store below 30°C.

Store in its original package to protect from humidity

Do not use any package that is damaged or shows signs of manipulation

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. Further information

Composition of Letrozole NORMON

The active substance is letrozole. Each tablet contains 2.5 mg of letrozole.

The other ingredients (excipients) are: lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycolate (of potato), talc, magnesium stearate, hydroxypropylmethylcellulose, hydroxypropylcellulose, cotton seed oil, iron oxide yellow, iron oxide red, and titanium dioxide.

Letrozole NORMON appearance and contents of the package

Letrozole NORMON is presented in the form of film coated tablets. The tablets are yellow, round and biconvex. Each package contains 30 tablets.

Marketing authorisation holder and Manufacture:

LABORATORIOS NORMON, S.A.

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

This text was last revised in June 2008