

Letrozole NEAPOLIS®

LETROZOLE 2.5 mg

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if the signs of illness are the same as yours.
- 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 4.

What is in this leaflet?

1. What is LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet and in which case it is used?
2. What you need to know before you take LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet?
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1. WHAT IS LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet AND IN WHICH CASE IS IT USED?

Pharmacotherapeutic Class: Endocrine treatments. Hormonal antagonists and related agents: aromatase inhibitor - ATC code: L02BG04.

What is LETROZOLE NEAPOLIS and how does it work?

LETROZOLE NEAPOLIS 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. The proliferation of breast cancer is frequently stimulated by oestrogens, which are female sex hormones. LETROZOLE NEAPOLIS reduces the amount of oestrogen by blocking an enzyme ("aromatase") involved in the production of oestrogens and therefore may block the growth of breast cancers that needs oestrogens to grow. As a result, the proliferation and / or spread of tumor cells to other parts of the body is slowed or stopped.

In which case is LETROZOLE NEAPOLIS used?

LETROZOLE NEAPOLIS is used to treat breast cancer in postmenopausal women, that is to say, who are no longer menstruating. LETROZOLE NEAPOLIS is used to prevent recurrence of breast cancer. It can be used as first-line treatment when immediate surgery is not adequate or if can be used as first-line treatment after breast surgery or after five years of tamoxifen treatment. LETROZOLE NEAPOLIS is also used to prevent the tumor from spreading to other parts of the body in patients with advanced breast cancer. If you have any questions about how LETROZOLE NEAPOLIS works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet?

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

Never take LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet if:

- you are allergic to letrozole or to any of the other ingredients of this medicine (listed in section 6),
- you still have periods, i.e. if you have not yet gone through the menopause,
- you are pregnant,
- you are breastfeeding.

If any of these conditions apply to you, do not take this medicine and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet:

- if you have a severe kidney disease,
- if you have a severe liver disease,
- if you have a history of osteoporosis or bone fractures (see also "Monitoring during LETROZOLE NEAPOLIS 2.5 mg film-coated tablet treatment" in section 3).

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

Children and adolescents

Children and adolescents should not use this medicine.

Elderly (65 years and over)

People aged 65 years and over can use this medicine at the same dose as for other adults.

Other medicines and LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet

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

LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet with food and drinks

Not applicable.

Pregnancy, breastfeeding and fertility

- You can only take LETROZOLE NEAPOLIS if you are menopausal. However, your doctor may discuss the need for effective contraception with you, knowing that you may still be of childbearing age and able to get pregnant with LETROZOLE NEAPOLIS.
- LETROZOLE NEAPOLIS is contraindicated in pregnancy or breastfeeding, as this may harm to your child.

Driving and using machines

If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet contains lactose.

LETROZOLE NEAPOLIS contains lactose (milk sugar). If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet?

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 usual dose is one tablet of LETROZOLE NEAPOLIS to be taken once a day. Taking LETROZOLE NEAPOLIS at the same time each day will help you remember to take your tablet. The tablet should be swallowed whole with a glass of water or other liquid, with or without food.

How long to take LETROZOLE NEAPOLIS 2.5 mg film-coated tablet?

Continue taking LETROZOLE NEAPOLIS daily for as long as your doctor has prescribed. You may be able to take it for several months or even years. If you have any questions about the duration of your treatment with LETROZOLE NEAPOLIS, tell your doctor.

Monitoring during treatment with LETROZOLE NEAPOLIS 2.5 mg film-coated tablets

You should only take this medicine under strict medical supervision. Your doctor will regularly monitor your health to determine if the treatment is having the expected effect. LETROZOLE NEAPOLIS may cause bone thinning or bone loss (osteoporosis) due to decreased estrogen in the body. Your doctor may decide to measure your bone density (a way to monitor osteoporosis) before, during and after treatment.

If you have taken more LETROZOLE NEAPOLIS 2.5 mg film-coated tablet than you should:

If you have taken too much LETROZOLE NEAPOLIS, or if another person has accidentally taken your tablets, ask for immediate advice by your doctor or in a hospital. Show them the blister pack. Medical treatment may be required.

If you forget to take LETROZOLE NEAPOLIS 2.5 mg film-coated tablet:

- If you notice your missed dose at an interval close to taking your next dose (for example 2 or 3 hours before), skip the missed dose and take the next dose at the usual time.
- Otherwise, take the dose as soon as you remember and then take the next pill as usual.
- Do not take a double dose to make up for the one that you missed.

If you stop taking LETROZOLE NEAPOLIS 2.5 mg film-coated tablet:

You should not stop taking LETROZOLE NEAPOLIS unless your doctor tells you to. See also the section above "How long to take LETROZOLE NEAPOLIS 2.5 mg film-coated tablet?"

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate and usually go away after a few days to a few weeks of treatment.

- Some of them, such as hot flashes, hair loss or vaginal bleeding, may be due to the lack of estrogen in the body.
- Do not be alarmed by this list of possible side effects. You may not have any.

Some side effects could be serious:

- Uncommon (may affect up to 1 in 100 people).
- Weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (signs of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched.
- Severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- Persistent severe blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed).

If you have any of the above, tell your doctor immediately.

You should tell your doctor immediately if you experience any of the side effects while taking LETROZOLE NEAPOLIS.

Letrozole NEAPOLIS®

LETROZOLE 2.5 mg

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

Letrozole NEAPOLIS	
Active substance (per tablet) Letrozole	2.5mg
Tablet Contents	Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium carboxymethyl starch, magnesium stearate, anhydrous colloidal silica, croscarmellose
Excipients	
Film-coating	Polyvinyl alcohol, polyethylene glycol / Macropol, titanium dioxide, talc, quinidine yellow, aluminum lacquer

What is LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet and content of the outer packaging
LETROZOLE NEAPOLIS comes in the form of film-coated tablets.

Each box contains 30 tablets in Alu / Alu blister.

Prescription and supply condition: List I

M.A. N°:

LETROZOLE NEAPOLIS 2.5mg. Box of 30 - 9390918H

Marketing authorization holder and manufacturer:

Neapolis Pharma

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THIS IS A MEDICINE

- A medicine is a product but not like the others.
- A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.
- Your doctor and pharmacist are familiar with the medicine, its indications and contraindications.
- Do not stop treatment on your own initiative during the prescribed period.
- Do not take it again, do not increase the doses without consulting your doctor.

KEEP THE MEDICINES OUT OF THE REACH OF CHILDREN

- Swelling of the face and neck (signs of an allergic reaction).
- Eyes and yellow skin, nausea, loss of appetite, dark urine (signs of hepatitis).
- Rash, redness of the skin, blisters on the lips, eyes or mouth, peeling skin, fever (signs of skin disorders).

Some side effects are very common (may affect more than 1 in 10 people).

- Hot flashes.
- Increased level of cholesterol (hypercholesterolaemia)
- Fatigue.
- Increased sweating.
- Pain in bones and joints (arthralgia).
- If you experience any of the mentioned side effects and it seems serious, please tell your doctor.

Some side effects are common (may affect up to 1 in 10 people).

- Skin rash
- Headache.
- Dizziness.
- Malaise (general feeling of not feeling well).
- Digestive problems, such as nausea, vomiting, indigestion, constipation, diarrhea.
- Increase or loss of appetite.
- Muscle aches.
- Thinning of the bones or weakening of the bone (osteoporosis) which can lead in some cases to bone fractures (see also section 3 "Monitoring during treatment with LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet").
- Swelling of the arms, hands, feet or ankles (edema).
- Depression.
- Weight gain.
- Hair loss.
- Increased blood pressure (hypertension).
- Abdominal pain.
- Dry skin.
- Vaginal bleeding.
- Palpitations, rapid heartbeat
- Joint stiffness (arthritis)
- Chest pain

If you experience any of the mentioned side effects and it seems serious, please tell your doctor.

Other side effects are uncommon (may affect up to 1 in 100 people).

- Nervous conditions, such as anxiety, nervousness, irritability, drowsiness, memory impairment, drowsiness, insomnia.
- Pain or burning sensation in the hand or wrist (carpal tunnel syndrome).
- Altered sensations, especially touch.
- Eye disorders, such as blurred vision, eye irritation.
- Skin disorders, such as itching (urticaria).
- Vaginal discharge or dryness.
- Breast pain.
- Fever.
- Thirst, altered taste, dry mouth.
- Dryness of the mucous membranes.
- Weight loss.
- Urinary tract infection, increased frequency of urination.
- Cough.
- Increased liver enzymes.
- Yellowing of the skin and eyes
- Increased blood levels of bilirubin (a breakdown product of red blood cells)
- side effects of unknown frequency (frequency cannot be estimated from the available data)
- Trigger finger, a condition that is manifested by a blockage of your finger or your thumb in a bent position.
- If you experience any of the mentioned side effects and it seems serious, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of the medicine.

5. HOW TO STORE LETROZOLE NEAPOLIS 2.5 mg, film-coated tablet?

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the package after EXP.

The expiration date refers to the last day of the month.

Do not store above 30 °C.

Store in the original packaging, protected from moisture.

Do not use this medication if the box is damaged or if you notice any signs of tampering.



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