Package leaflet: Information for the user

Letrozin 2,5 mg, filmomhulde tabletten
letrozole

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 their 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 LETARSIS is and what it is used for

What LETARSIS is and how it works
Letarsis 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. Growth of breast cancer is frequently stimulated by oestrogens, which are female sex hormones. Letarsis reduces the amount of oestrogen by blocking an enzyme ("aromatase") involved in the production of oestrogens and therefore may block the growth of breast cancer that needs oestogens to grow. As a consequence tumour cells slow or stop the growing and/or spreading to other parts of the body.

What LETARSIS is used for
Letarsis is used to treat breast cancer in women who have gone through menopause i.e cessation of periods.

It is used to prevent breast cancer happening again. It can be used as a first treatment before breast cancer surgery in case immediate surgery is not suitable or it can be used as first treatment after breast cancer 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 advanced breast cancer.

If you have any questions about how Letarsis works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take LETARSIS

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

Do not take LETARSIS
- if you are allergic to letrozole or to any of the other ingredients of of this medicine (listed in section 6),
- if you still have periods, i.e. if 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**, do not take this medicine and talk to your doctor.**

Warnings and precautions
Talk to your doctor or pharmacist before taking LETARSIS
- if you have a severe liver disease,
- if you have a severe kidney disease,
- if you have a history of osteoporosis or bone fractures (see also "Follow-up during Letarsis 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 Letarsis.

Children and adolescents (below 18 years)
Children and adolescents should not use this medicine.

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

Pregnancy, breast-feeding and fertility
- You should only take LETARSIS when you have gone through the menopause. However, your doctor should discuss with you about using effective contraceptive, as you may still have the potential to become pregnant during treatment with LETARSIS.
- You must not take LETARSIS if you are pregnant or breast-feeding as it may harm your baby.

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.

LETARSIS contains lactose
LETARSIS contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take LETARSIS

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 Letarsis taken once a day. Taking LETARSIS at the same time each day will help you remember when to take your tablet.

The tablet can be taken with or without food and should be swallowed whole with a glass of water or another liquid.

How long to take LETARSIS
Continue taking LETARSIS 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 LETARSIS talk to your doctor.

Follow-up during LETARSIS treatment
You should only take this medicine under strict medical supervision. Your doctor will regularly monitor your condition to check whether the treatment is having the right effect.

LETARSIS may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may decide to measure your bone density (a way of monitoring for osteoporosis) before, during and after treatment.

If you take more LETARSIS than you should
If you have taken too much LETARSIS or if someone else accidentally took your tablets, contact your doctor, pharmacy or hospital for advice immediately. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take LETARSIS
- **If it is almost time for your next dose (e.g within 2 or 3 hours)** skip the dose you missed and take your next dose when you are meant to.
- Otherwise, take the dose as soon as your remember, and then take the next tablet as you would normally.

Do not take a double dose to make up for the one that you missed.

If you stop taking LETARSIS
Do not stop taking LETARSIS unless your doctor tells you to. See also the section above "How long to take LETARSIS".

4. Possible side effects

Like all medicines, this medicine 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 to a few weeks of treatment.

Some of these side effects, such as hot flushes, hair loss or vaginal bleeding, may be due to the lack of oestrogens in your body.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Some side effects could be serious:
Rare or uncommon side effects (i.e. they may affect between 1 to 100 in every 10,000 patients):
- 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 (sign of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
- 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).
- 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).
- Severe persistent blurred vision.

If any of the above occurs, tell your doctor straight away.

You should also inform the doctor straight away if you experience any of the following symptoms during treatment with LETARSIS:

- Swelling mainly of the face and throat (signs of allergic reaction).
- Yellow skin and eyes, nausea, loss of appetite, dark-coloured urine (signs of hepatitis).
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

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

- Hot flushes
- Increased level of cholesterol (hypercholesterolaemia)
- Fatigue
- Increased sweating
- Pain in bones and joints (arthralgia)

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

Some side effects are common. These side effects may affect between 1 to 10 in every 100 patients.
- Skin rash
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea
- Increase in or loss of appetite
- Pain in muscles
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also "Follow-up during LETARSIS treatment" in section 3)
- Swelling of arms, hands, feet, ankles (oedema)
- Depression
- Weight increase
- Hair loss
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding

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

Other side effects are uncommon These side effects may affect between 1 to 10 in every 1,000 patients.
- Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- Impairment of sensation, especially that of touch
- Eye disorders such as blurred vision, eye irritation
- Palpitations, rapid heart rate
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- Joint stiffness (arthritis)
- Breast pain
- Fever
- Thirst, taste disorder, dry mouth
- Dryness of mucous membranes
- Weight decrease
- Urinary tract infection, increased frequency of urination
- Cough
- Increased level of enzymes

Side effects with frequency not known
Trigger finger, a condition in which your finger or thumb catches in bent position.

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store LETARSIS

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton 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 to protect the environment.

6. Contents of the pack and other information

What LETARSIS contains

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are lactose monohydrate, cellulose microcrystalline (E460), maize starch pregelatinised, sodium starch glycolate, magnesium stearate (E572), colloidal silicon dioxide (E551). The ingredients in the tablet coating are macrogol, talc (E553b), hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172).

What LETARSIS looks like and contents of the pack
LETARSIS is a yellow film-coated round tablet, inscripted with L9OO at one side and 2.5 on the other side.
LETARSIS is available in blisters of 10, 28, 30, 50, 60, 84, 90, 98 or 100 tablets per box.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen:

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Fabrikanten:

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Ostenfelder Straβe 51-61, 59320, Ennigerloh
DUITSLAND

SYNTHON HISPANIA S.L.
Castello 1, Poligono Las Salinas, 08830, Sant Boi de Llobregat,
SPANJE

SYNTHON B.V.
Microweg 22, Nijmegen, 6545 CM
NEDERLAND

PHARMATHEN S.A.
Dervenakion 6, Pallini, Attiki, 15351,
GRIEKENLAND

In het register ingeschreven onder
RVG 100811

This medicinal product is authorised in the Member States of the EEA under the following names:

Greece	Letrozin 2,5 mg επικαλυμμένα με λεπτό υμένιο δισκία
The Netherlands	Letarsis 2,5 mg film-coated tablets

Deze bijsluiter is voor het laatst goedgekeurd in mei 2016