Package leaflet: Information for the patient

Letrozol Sandoz® 2,5 mg, filmomhulde tabletten

letrozol

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 [Nationally approved name] is and what it is used for

What [Nationally approved name] is and how it works
[Nationally approved name] 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. [Nationally approved name] 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 oestrogens to grow. As a consequence tumour cells slow or stop growing and/or spreading to other parts of the body.

What [Nationally approved name] is used for
[Nationally approved name] is used to treat breast cancer in women who have gone through menopause i.e. cessation of periods.
It is used to prevent cancer from happening again. It can be used as 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 treatment with tamixofen. [Nationally approved name] 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 [Nationally approved name] works or why this medicine has been prescribed for you, ask your doctor.

2 What you need to know before you take [Nationally approved name]
Follow all the doctor's instructions carefully. They may differ from the general information in this leaflet.

Do not take [Nationally approved name]
- if you are allergic to letrozole or to any of the other ingredients 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 [Nationally approved name]
- 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 "Follow-up during [Nationally approved name] 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 [Nationally approved name].

Letrozole may cause inflammation in tendons or tendon injury (see section 4). At any sign of tendon pain or swelling – rest the painful area and contact your doctor.

Children and adolescents (below 18 years)

Children and adolescents should not use this medicine.

Older people (age 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 [Nationally approved name]

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 [Nationally approved name] 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 [Nationally approved name].
- You must not take [Nationally approved name] 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.

[Nationally approved name] contains lactose

[Nationally approved name] contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

[Nationally approved name] contains less than 1 mmol sodium (23 mg) per film-coated tablet 2.5 mg, that is to say essentially 'sodium-free'.

3 How to take [Nationally approved name]

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 [Nationally approved name] to be taken once a day. Taking [Nationally approved name] 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 [Nationally approved name]
Continue taking [Nationally approved name] 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 [Nationally approved name], talk to your doctor.

Follow-up during [Nationally approved name] 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.
[Nationally approved name] 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 [Nationally approved name] than you should
If you have taken too much [Nationally approved name], or if someone else accidentally takes your tablets, contact a doctor or hospital for advice immediately. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take [Nationally approved name]
- 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 [Nationally approved name]
Do not stop taking [Nationally approved name] unless your doctor tells you to. See also the section above “How long to take [Nationally approved name]”.

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:
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 (sign of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
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- 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.

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 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 [Nationally approved name]:
- 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: may affect more than 1 in 10 people**:**
- 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: may affect up to 1 in 10 people**:**
- Palpitations, rapid heart rate
- Joint stiffness (arthritis)
- Chest pain
- 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 [Nationally approved name] 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: may affect up to 1 in 100 people.
- 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
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- 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
- Yellowing of the skin and eyes
- High blood levels of bilirubin (a breakdown product of red blood cells)
- inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)

Other side effects are rare (may affect up to 1 in 1,000 people):
- rupture of a tendon (connective tissues that connect muscles to bones)

Side effects with frequency not known (frequency cannot be estimated from the available data) 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 [Nationally completed name]

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 blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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 [Nationally completed name] 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, sodium starch glycolate, magnesium stearate (E572) and silica colloidal anhydrous (E551). The ingredients in the tablet coating are hypromellose (E464), talc (E553b), macrogol (PEG 8000), titanium dioxide (E171) and iron oxide yellow (E172).

What [Nationally completed name] looks like and contents of the pack

The film-coated tablets are dark-yellow and round. They are marked with “FV” on one side and “CG” on the other side.
Each Alu/PVC/PE/PVDC blister pack contains 10, 14, 28, 30, 50, 56, 60, 84, 90, 98, 100, 100 (10 x 10), 112 or 120 film coated tablets. 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
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant:
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Novartis Farma S.P.A.
Via Provinciale Schito 131
80058 Torre Annunziata (NA)
Italië

In het register ingeschreven onder:
Letrozol Sandoz 2,5 mg, filmomhulde tabletten is in het register ingeschreven onder RVG 106323.

Dit geneesmiddel is geregistreerd in de lidstaten van de EEA onder de volgende namen:
Nederland: Letrozol Sandoz 2,5 mg, filmomhulde tabletten

Duitsland: Letrozol – 1 A Pharma 2,5 mg Filmtabletten

Deze bijsluiter is voor de laatste keer goedgekeurd in februari 2024