PACKAGE LEAFLET

Package leaflet: Information for the user

Letrozole 2.5 mg film-coated tablets

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 Letrozole is and what it is used for
2. What you need to know before you take Letrozole
3. How to take Letrozole
4. Possible side effects
5. How to store Letrozole
6. Contents of the pack and other information

1. What Letrozole is and what it is used for

What Letrozole is and how it works
Letrozole 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. Letrozole 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 Letrozole is used for
Letrozole 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 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 Letrozole works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Letrozole

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

Do not take Letrozole
- 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 Letrozole
- 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 Letrozole 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.

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 Letrozole
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 and breast-feeding
- You should only take Letrozole when you have gone through the menopause. However, your doctor should discuss with you about using effective contraception, as you may still have the potential to become pregnant during treatment with Letrozole .
- You must not take Letrozole 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.

Letrozole contains lactose
Letrozole 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 medicine.

3. How to take Letrozole

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 to be taken once a day. Taking Letrozole 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 Letrozole
Continue taking Letrozole 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, talk to your doctor.

Follow-up during Letrozole 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.

Letrozole 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 Letrozole than you should
If you have taken too much Letrozole, 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 Letrozole
- 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 you remember, and then take the next tablet as you would normally.
- Do not take a double dose to make up for a forgotten dose.

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

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 (may affect up to 1 in 1,000 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)
- 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 Letrozole:
- 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 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. These side effects may affect up to 1 in 10 people.
- 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 Letrozole 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
- palpitations, rapid heart rate
- joint stiffness (arthritis)
- chest pain.

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

Other side effects are uncommon. These side effects 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).

Rare side effects. These side effects may affect up to 1 in 1,000 people.
- rupture of a tendon (connective tissues that connect muscles to bones).

Side effects with frequency unknown (the frequency cannot be determined based on the available data).
- trigger finger, a condition in which your finger or thumb catches in a 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 side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Letrozole

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

This medicinal product does not require any special storage conditions.

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. Contents of the pack and other information

What Letrozole contains
- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose (E460), maize starch, povidone (K-30), sodium starch glycolate type-A, silica, colloidal anhydrous, magnesium stearate (E572).
- Tablet coating contains: hydroxypropylmethylcellulose (E464), iron oxide yellow (E172), titanium dioxide (E171), polyethylene glycol 4000, talc, polyethylene glycol 400.

What Letrozole looks like and contents of the pack
Letrozole 2.5 mg film-coated tablets are dark yellow, round, biconvex, film-coated tablets plain on both sides.

The tablets are marketed in PVC/Aluminium transparent blisters of 28, 30, 60, 84 or 100 pieces.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

France:	Letrozole CRISTERS PHARMA 2.5 mg comprimés pelliculés
Germany:	Letrozol SUN 2.5 mg Filmtabletten
Italy:	Letrozolo SUN 2.5 mg compresse rivestite con film
Spain:	Letrozol SUN 2.5 mg comprimidos recubiertos con película EFG
The Netherlands:	Letrozol SUN 2.5 mg filmomhulde tabletten
United Kingdom (Northern Ireland):	Letrozole 2.5 mg film-coated tablets

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