

## Package leaflet: Information for the user

### Letrozole 2.5 mg film coated tablets

Letrozole

The name of your medicine is Letrozole 2.5 mg film coated tablets, which will be referred to as Letrozole tablets throughout the rest of this document.

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

#### **1. What Letrozole tablets is and what it is used for**

Letrozole 2.5 mg film coated tablets contain an active substance called letrozole. Letrozole belongs to a group of medicines called aromatase inhibitors. It is a hormonal (endocrine) breast cancer treatment.

Letrozole tablets are used to

- prevent breast cancer recurrences as first treatment after breast surgery or following five years of treatment with tamoxifen
- prevent breast tumours spreading to other parts of the body in patients in advanced stages of the disease

#### **Letrozole tablets should be used only for oestrogen receptor-positive breast cancer and only in women after menopause (when your periods have stopped completely).**

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

Letrozole tablets should only be taken under strict medical supervision. Your doctor will regularly monitor your condition to check if the treatment is having the desired effect. Letrozole tablets may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body (see *Section 4 – Possible side effects*). Your doctor may therefore decide to measure your bone density before, during and after treatment. If you have any questions about how Letrozole tablets work or why this medicine has been prescribed for you, ask your doctor.

## 2. What you need to know before you take Letrozole tablets

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

### **Do not take Letrozole tablets**

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

If any of the above conditions apply to you, **tell your doctor before taking Letrozole tablets.**

### **Warning and precautions**

Take special care with Letrozole tablets and talk to your doctor if you have

- a severe kidney disease
- a severe liver disease
- a history of osteoporosis or bone fractures

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

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)**

Letrozole tablets are not to be used in children or adolescents.

### **Elderly (age 65 years and over)**

Letrozole tablets can be used by people aged 65 years and over. The dose is the same for older people as it is for other adults.

### **Other medicines and Letrozole tablets**

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

### **Letrozole tablets with food and drink**

Letrozole tablets can be taken with or without food or a drink.

### **Pregnancy and breast-feeding**

You must not take Letrozole tablets if you are pregnant or breast feeding as it may harm your baby. If you are pregnant or are currently breast-feeding, tell your doctor before taking Letrozole tablets. However, since Letrozole tablets are only recommended for postmenopausal women, pregnancy and breast-feeding restrictions most likely will not apply to you. However, if you recently became postmenopausal or if you are perimenopausal, your doctor should discuss with you about the necessity of a pregnancy test before taking letrozole and of a contraception as you might have the potential to become pregnant.

### **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.

## 3. How to take Letrozole tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or your pharmacist if you are not sure.

### **Dosage**

The usual dose is one tablet taken once a day. Taking Letrozole tablets at the same time each day will help you remember when to take your tablet.

### **Method of administration**

The tablet should be swallowed whole with a glass of water or another liquid.

### **Duration of treatment**

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

### **If you take more Letrozole tablets than you should**

If you have taken too much Letrozole tablets, or if someone else accidentally takes your tablets, contact your doctor or hospital for advice immediately. Show them the pack of tablets. Medical treatment may be necessary.

### **If you forget to take Letrozole tablets**

- 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 the one that you missed.

### **If you stop taking Letrozole tablets**

Do not stop taking Letrozole tablets unless your doctor tells you. See also the section above “Duration of treatment”.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **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 them, 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.

### **Serious side effects**

These side effects are rare or uncommon (affect less than 1 in every 100 patients), but do require **immediate medical attention**.

- some patients experienced swelling mainly of the face and throat (signs of allergic reaction) during treatment with Letrozole tablets
- weakness, paralysis, loss of feeling in an arm or leg or any other part of the body, loss of coordination, nausea, difficulty in speaking or breathing (sign of a brain disorder, such as a stroke)
- sudden oppressive chest pain (sign of a heart disorder)
- difficulty in breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, sudden arm or leg (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 you are having any of the above, tell your doctor straight away.**

Other reported side effects

**Very common side effects** (affect more than 10 in every 100 patients)

- hot flushes
- fatigue
- increased sweating
- pain in bones and joints (arthralgia)

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

**Common side effects** (may affect between 1 and 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
- swelling of arms, hands, feet, ankles (oedema)
- sad mood (depression)
- weight increase
- hair loss
- palpitations, rapid heart rate
- joint stiffness (arthritis)
- chest pain

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

**Uncommon side effects** (may affect between 1 and 10 in every 1,000 patients)

- nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- impairment of sensation, especially that of touch
- eye disorders such as blurred vision or eye irritation
- yellowing of the skin and eyes
- raised blood pressure (hypertension)
- high blood levels of bilirubin (a breakdown product of red blood cells)
- skin disorders such as itching (urticaria), dry skin
- vaginal disorders such as bleeding, discharge or dryness
- abdominal pain
- breast pain
- fever
- thirst, taste disorder, dry mouth
- dryness of mucous membranes
- weight decrease
- urinary tract infection, increased frequency of urination
- cough
- inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)

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

**Rare side effects** (may affect between 1 and 10 in every 10,000 patients)

- rupture of a tendon (connective tissues that connect muscles to bones)
- pulmonary embolism
- arterial thrombosis
- cerebrovascular infarction

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

You may also have some blood test disorders while taking Letrozole tablets, such as high levels of cholesterol (hypercholesterolemia) or high levels of liver enzymes.

### **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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 tablets**

**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 and the blister after EXP. 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 protect the environment.

## **6. Contents of the pack and other information**

### **What Letrozole tablets contains:**

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are cellulose microcrystalline, silica colloidal anhydrous, sodium starch glycolate, and magnesium stearate. The coating is composed of polyvinyl alcohol, polyethylene glycol, titanium dioxide (E171), talc, yellow iron oxide (E172), Sunset Yellow FCF (E110).

### **What Letrozole tablets looks like and contents of the pack**

Letrozole tablets are supplied as film-coated tablets. The film-coated tablets are yellow and round, biconvex in shape, with "2.5" imprinted on one side of the tablet and plain on the reverse. Each blister pack contains 10, 14, 28, 30, or 100 film-coated tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

The marketing authorisation holder is  
Hikma Farmacêutica (Portugal), S.A.  
Estrada do Rio da Mó n.º 8, 8A e 8B, Ferveça  
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or

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153 51 Pallini  
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**This medicinal product is authorised in the Member States of the EEA under the following names:**

Portugal – Letrozol Hikma  
United Kingdom – Letrozole 2.5 mg film-coated tablets

**This leaflet was last revised in: 09/2019.**