

## **Package leaflet: Information for the user**

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

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

#### **What Letrozole Medipha Santé is and how it works**

Letrozole Medipha Santé contains an active substance called letrozole. It belongs to a group of medicines called aromatase inhibitors. It is an hormonal (or “endocrine”) breast cancer treatment. Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. Letrozole Medipha Santé 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 Medipha Santé is used for**

Letrozole Medipha Santé 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 Medipha Santé 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 Medipha Santé works or why this medicine has been prescribed for you, ask your doctor.

### **2. What you need to know before you take Letrozole Medipha Santé**

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

**Do not take Letrozole Medipha Santé:**

- if you are allergic to letrozole or 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 Medipha Santé

- 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 Medipha Santé 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 Medipha Santé.

**Children and adolescents (below 18 years)**

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 Medipha Santé**

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 must not take Letrozole Medipha Santé if you are pregnant or breast-feeding, as this may harm your baby.
- You should only take Letrozole Medipha Santé when you have gone through the menopause. However, your doctor should discuss with you the use of effective contraception, as you may still have the potential to become pregnant during treatment with Letrozole Medipha Santé.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

If you feel dizzy, tired, drowsy or generally unwell, don't drive or operate any tools or machines until you feel normal again.

**Letrozole Medipha Santé contains lactose.** If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take Letrozole Medipha Santé**

Always take use 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 Medipha Santé daily. Taking Letrozole Medipha Santé at the same time each day will help you remember when to take your tablet.

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

#### **How long to take Letrozole Medipha Santé**

Continue taking Letrozole Medipha Santé every day 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 Medipha Santé, talk to your doctor.

#### **Follow-up during Letrozole Medipha Santé 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 Medipha Santé 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 Medipha Santé than you should**

If you have taken too much of Letrozole Medipha Santé 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 Medipha Santé**

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 Medipha Santé**

Do not stop taking Letrozole Medipha Santé unless your doctor tells you to. See also the section above “How long to take Letrozole Medipha Santé”.

### **4. Possible side effects**

Like all medicines, Letrozole Medipha Santé can cause side effects, although not everybody gets them.

Most of the side effects are mild or 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 Letrozole Medipha Santé:

- 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 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 Letrozole Medipha Santé 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 beat
- 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 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 possible side effects not listed 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 this medicine.

### **5. How to store Letrozole Medipha Santé**

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 blister 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 use any pack that is damaged or shows signs of tampering.

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 Medipha Santé contains**

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are :
  - Core tablet  
Lactose monohydrate, microcrystalline cellulose, maize starch, sodium starch glycolate, silica colloidal anhydrous, magnesium stearate
  - Film-coating  
Opadry yellow 02B38014 [titanium dioxide (E171), iron oxide yellow (E172), macrogol 4000, iron oxide red (E172), talc, hypromellose]

### **What Letrozole Medipha Santé looks like and contents of the pack**

Letrozole Medipha Santé tablets are yellow, round, biconvex, film-coated tablets.

Letrozole Medipha Santé tablets are packed in blisters of : 10, 14, 28, 30 or 100 film-coated tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

#### **MEDIPHA SANTE**

Les Fjords - Immeuble Oslo  
19 avenue de Norvège  
91953 Courtaboeuf Cedex  
FRANCE

### **Manufacturer**

#### **GENEPHARM SA**

18<sup>th</sup> Km, Marathonos avenue  
15351 Pallini Attikis  
GREECE

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

|                 |                                                        |
|-----------------|--------------------------------------------------------|
| Denmark:        | Letrozol Medipha Santé 2,5 mg filmovertrukne tabletter |
| Ireland:        | Letrozole Medipha Santé 2.5 mg film-coated tablets     |
| United Kingdom: | Letrozole 2.5 mg film-coated tablets                   |

**This leaflet was last approved in 03/2016**