PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Letrozole Teva Tablets

Composition
Each tablet contains:
Letrozole 2.5 mg
For information regarding inactive ingredients and allergens, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".
Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

- Adjuvant treatment for early-stage breast cancer in postmenopausal women.
- Extended adjuvant treatment for early breast cancer in postmenopausal women following standard adjuvant tamoxifen therapy.
- Treatment of advanced or metastatic breast cancer in postmenopausal women.
- Treatment of advanced breast cancer in postmenopausal women with disease progression after treatment with anti-estrogens.

Therapeutic class
Aromatase inhibitors (anti-estrogens).
The medicine is a hormonal treatment (also called "endocrine therapy") for breast cancer.
Development of breast cancer is often stimulated by estrogens, which are female sex hormones. Letrozole Teva reduces the amount of estrogen by blocking an enzyme ("aromatase") that is involved in estrogen production, and can therefore block the growth of cancerous tissues in the breast that need estrogen to grow. As a result, the cancer cells slow or stop their development and/or spreading to other parts of the body.
If you have any questions regarding how Letrozole Teva works or why it has been prescribed for you, refer to your doctor.

2. Before using the medicine

You should carefully follow all of the doctor's orders. They may differ from the general information provided in this leaflet.

Do not use this medicine if:
- You are allergic (hypersensitive) to letrozole or to any of the additional ingredients contained in this medicine (see section 6 in this leaflet – "Additional information").
- You are still getting menstrual periods, namely, if you still have not reached menopause.
- You are pregnant.
- You are breastfeeding.

If any of these conditions applies to you, do not take the medicine and refer to your doctor.

Special warnings regarding the use of the medicine
Before treatment with Letrozole Teva, tell the doctor if:
- You suffer from a severe kidney disease.
- You suffer from a severe liver disease.
- You have a history of osteoporosis or bone fractures (see also section 2 - "Tests and follow-up").

Inform your doctor if any of these conditions applies to you. Your doctor will take this information into consideration during treatment with Letrozole Teva.
Letrozole may cause tendon inflammation or tendon damage (see section 4). Upon any sign of tendon swelling or pain, allow the painful area to rest and contact your doctor.
Children and adolescents (under the age of 18)
This medicine is not intended for use in children and adolescents under the age of 18.
The elderly (ages 65 and above)
Patients aged 65 years and older can use Letrozole Teva in the same dosage as other adult women.
Tests and follow-up
Letrozole Teva should only be taken under strict medical supervision.
Your doctor will routinely monitor your condition in order to check if the treatment is having the desired effect.
Letrozole Teva may cause bone thinning or wasting (osteoporosis) due to the reduction of estrogen in your body. Your doctor may decide to measure your bone density (which is a way to monitor osteoporosis) before, during or after treatment.
Drug-drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:
- Tamoxifen
- Medicines containing other anti-estrogens or medicines containing estrogens
- Phenytoin
- Clopidogrel

Use of the medicine and food
The tablet can be taken with or without food.
Pregnancy, breastfeeding and fertility
- Take Letrozole Teva only if you have gone through 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 Teva.
- Do not take Letrozole Teva if you are pregnant or breastfeeding, as it may harm your baby.

Driving and operating machinery
Do not drive or operate tools/machinery if you feel dizzy, tired or drowsy, or if you feel generally unwell, until you feel these effects have passed.
Important information about some of the ingredients of the medicine
- Letrozole Teva contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.
- Letrozole Teva contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.
- Letrozole Teva tablets contain FD&C yellow #5 / tartrazine aluminum lake, which may cause an allergic reaction.

See also section 6 - "Additional information".

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is one tablet of Letrozole Teva per day.
Do not exceed the recommended dose.
Duration of treatment
You should continue to take Letrozole Teva every day for the period of time prescribed to you by your doctor.
You may need to take the medicine for months or even years.
If you have any questions about how long you will need to continue using Letrozole Teva, refer to your doctor.
How to take the medicine
Swallow the tablet whole with a glass of water or other liquid.
There is no information regarding pulverization, halving or chewing the tablet.
Taking Letrozole Teva at the same time every day will help you remember when to take the tablet.
If you accidentally took a higher dosage
If you took an overdose, or if a child or anyone else has accidentally swallowed this medicine, refer immediately to the doctor or to a hospital emergency room and bring the package of the medicine with you. Medical attention may be required.
If you have forgotten to take the medicine
If you forgot to take this medicine at the scheduled time and the time for the next dose is close (i.e., in 2-3 hours), skip the missed dose and take the next dose at the usual time.
Otherwise, take a dose as soon as you remember, and then take the next tablet at the usual time.
Do not take a double dose in order to compensate for the dose you forgot.
Follow the treatment as recommended by the doctor.
If you stop taking Letrozole Teva
Do not stop treatment with the medicine without consulting the doctor. See also the section "Duration of treatment" above.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of Letrozole Teva may cause side effects in some users.
Do not be alarmed when reading the list of side effects, you may not experience any of them.
Most of the side effects are mild to moderate and will usually disappear after a few days to a few weeks of treatment.
Some of the side effects, such as hot flashes, hair loss or vaginal bleeding, can be caused due to the estrogen deficiency in your body.
Side effects that may be severe:
You should refer to the doctor immediately if you have any of the following conditions:
Uncommon side effects (side effects that occur in 1-10 out of 1,000 users):
- Weakness, paralysis or loss of feeling in any part of the body (particularly in the 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).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched.
- Very high fever, chills or mouth ulcers due to infections (white blood cell deficiency).
- Severe persistent blurred vision.
- Inflammation in a tendon or tendons (connective tissues that connect the muscles to the bones).

Rare side effects (side effects that occur in 1-10 out of 10,000 users):
- Breathing difficulties, chest pain, fainting, rapid heartbeat, bluish skin or a sudden pain in the arm, leg or foot (signs of a possible blood clot).
- Tendon rupture (connective tissues that connect the muscles to the bones).

In addition, inform the doctor immediately if you suffer from any of the following symptoms during the course of treatment with Letrozole Teva:
- Swelling mainly of the face and throat (signs of allergic reaction).
- Yellow skin and eyes, nausea, loss of appetite, dark-colored urine (signs of liver inflammation - hepatitis).
- Rash, red skin, blistering on the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

Additional side effects:
Very common side effects (side effects that occur in more than one out of ten users):
- Hot flashes
- High level of cholesterol (hypercholesterolemia)
- Fatigue (including weakness [generally feeling unwell])
- Increased sweating
- Joint and bone pain (arthralgia)

If one or more of these side effects affects you severely, refer to your doctor.
Common side effects (side effects that occur in 1-10 out of 100 users):
- Skin rash
- Headache
- Dizziness
- Gastrointestinal disturbances such as nausea, vomiting, constipation, diarrhea, digestive difficulties
- Muscle pain
- Increase or loss of appetite
- Bone thinning or wasting (osteoporosis), leading to bone fractures in certain cases (see also section 2 - "Tests and follow-up")
- Swelling of the arms, hands, feet and ankles (edema)
- Depression
- Weight gain
- Hair loss
- Rise in blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding
- Palpitations, rapid heartbeat
- Joint stiffness (arthritis)
- Chest pain

If one or more of these side effects affects you severely, refer to your doctor.
Uncommon side effects (side effects that occur in 1-10 out of 1,000 users):
- Disturbances related to the nervous system, such as anxiety, nervousness, irritability, drowsiness, memory impairment, somnolence, insomnia
- Pain or burning sensation in the hands or wrists (carpal tunnel syndrome)
- Impairment of sensation, especially that of touch
- Eye impairment such as blurred vision, eye irritation
- Skin disorder such as itching (urticaria)
- Vaginal discharge or dryness
- Breast pain
- Fever
- Thirst, impairment of taste sensation, dry mouth, dryness of mucous membranes
- Weight loss
- Urinary tract infection, increased frequency of urination
- Cough
- Increased level of enzymes
- Yellowing of the skin and the eyes, high levels of bilirubin in the blood (a product of the metabolism of red blood cells)

Side effects with unknown frequency (frequency cannot be estimated from existing data):
- Trigger finger, a condition in which the finger or thumb gets stuck in a bent position.

If one or more of these side effects affects you severely, refer to your doctor.
If a side effect occurs, if any of the side effects persists or worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor immediately.
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (Exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place under 25°C.**
- Store in the original package to protect from light.
- Do not use if the package is damaged or shows signs of tampering.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, starch, sodium starch glycolate, polyvinyl alcohol, colloidal anhydrous silica, magnesium stearate, titanium dioxide, macrogol/ PEG 3350, talc, iron oxide yellow, FD&C yellow #5/tartrazine aluminum lake, FD&C blue #2/indigo carmine aluminum lake.
Each tablet of Letrozole Teva contains: 64 mg lactose, 0.3 mg sodium.
What does the medicine look like and what are the contents of the package:
A dark yellow, round tablet, with "93" debossed on one side and "B1" on the other side.
The pack contains 28 or 30 tablets. Not all package sizes may actually be marketed.
Manufacturer, license holder and the address
Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva
This leaflet was revised in June 2020.
Registration number of the medicine in the national drug registry of the Ministry of Health: 142.28.31878

Letrozole PIL MW1020

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