

This medicine can be sold with a physician's prescription only

Letrozole Dexcel, coated tablets, 2.5 mg

Active ingredient: Each coated tablet contains Letrozole 2.5 mg.

Inactive ingredients and allergens in the medicine - see section 6 'Additional information' and in section 2 'Important information about some of the ingredients of this medicine'.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think 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 stage breast cancer in postmenopausal women following standard adjuvant treatment with tamoxifen.
- Treatment of advanced or metastatic breast cancer in postmenopausal women.
- Treatment of advanced breast cancer in postmenopausal women with progression of the disease following treatment with anti-estrogens.

Therapeutic group: Aromatase inhibitors (anti-estrogens).

The medicine is a hormonal (also called "endocrine") breast cancer treatment. The development of breast cancer is frequently stimulated by estrogens, which are female sex hormones. **Letrozole Dexcel** reduces the amount of estrogens by blocking an enzyme ("aromatase") involved in the production of estrogens, and therefore can block the growth of breast cancers which require estrogen for their growth. As a result, the cancer cells slow down or stop developing and/or spreading to other parts of the body. If you have any questions about how Letrozole Dexcel works or why it has been prescribed for you, refer to your doctor.

2. Before using the medicine

All of the doctor's instructions must be carefully followed. They may be different than the general information that appears in this leaflet.

Do not use the medicine if:

- You are allergic (hypersensitive) to the active ingredient (Letrozole) or to any of the additional ingredients this medicine contains (see section 6).
- You still have menstrual period, i.e., if you have not yet gone through menopause.
- You are pregnant.
- You are breastfeeding.

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

Special warnings regarding the use of the medicine

Before the treatment with Letrozole Dexcel, tell the doctor if:

- You have a severe kidney disease.
- You have a severe liver disease.
- You have a history of osteoporosis or bone fractures (see also in section 2 'Tests and follow-up').

Tell the doctor if any of these conditions applies to you. Your doctor will take this information into consideration during the treatment with **Letrozole Dexcel**.

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

Children and adolescents (under the age of 18) This medicine is not intended for children and adolescents under the age of 18.

Elderly (65 years of age and older): Patients 65 years of age and older can use **Letrozole Dexcel** at the same dosage as other adults.

Tests and follow-up **Letrozole Dexcel** should only be taken under strict medical supervision.

Your doctor will regularly monitor your condition in order to check whether the treatment is having the desired effect. **Letrozole Dexcel** may cause thinning or wasting of your bones (osteoporosis) due to a reduction of estrogen in your body. Your doctor may decide to measure your bone density (a way of monitoring osteoporosis) before, during, or after the treatment.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- tamoxifen
- treatments containing other anti-estrogens or estrogens
- phenytoin
- clodigrel

Use of this medicine and food

The medicine can be taken with or without food.

Pregnancy, breastfeeding and fertility

• Letrozole Dexcel should only be taken if you have gone through menopause. However, your doctor should discuss the use of effective contraception with you as you may still have the potential to become pregnant during the treatment with **Letrozole Dexcel**.

Do not take **Letrozole Dexcel** if you are pregnant or breastfeeding as it may harm your baby.

Driving and using machines

Do not drive or operate any tools/machines if you feel dizziness, tiredness, drowsiness, or you feel generally unwell, until you feel that these effects have passed.

Important information about some of the ingredients of this medicine

The medicine contains lactose. If you have been told in the past by a doctor that you have an intolerance for certain sugars, consult a doctor before starting treatment with this medicine.

This medicine contains less than 1 millimole of

sodium (23 mg) per tablet, i.e. it is essentially "sodium free".

3. How should you use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage is one tablet of **Letrozole Dexcel** once daily.

Do not exceed the recommended dose.

Method of administration

Swallow the tablet whole with a glass of water or other liquid.

Do not chew the tablet as it is a coated tablet. There is no information about crushing. Do not halve the tablet as it has no score line. Taking **Letrozole Dexcel** at the same time each day will help you remember when to take the tablet.

Duration of treatment

Continue taking **Letrozole Dexcel** every day for as long as your doctor tells you. You may need to take the medicine for months or even years. If you have any questions regarding the length of time for which you will have to continue using **Letrozole Dexcel**, refer to your doctor.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child or anyone else has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Medical treatment may be needed.

If you forgot to take the medicine

- If the time for the next dose is close (i.e., within 2 or 3 hours), skip the dose you missed, and take the next dose at the regular time.
- Otherwise, take a dose as soon as you remember, and then take the next dose at the regular time.

Do not take a double dose to make up for the forgotten dose.

If you stop taking the medicine

Do not stop treatment with the medicine without consulting the doctor. See also the above in section "Duration of treatment."

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Letrozole Dexcel** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from 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 flushes, hair loss, or vaginal bleeding, may be caused as a result of a lack of estrogens in your body.

Side effects that can be severe:

Refer to your doctor immediately if you suffer from one of the following conditions:

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):

- Weakness, paralysis or the loss of feeling in any part of the body (especially in an arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (a sign of a brain disorder, e.g. a stroke).
- Sudden oppressive chest pain (a sign of a cardiac disorder).
- Swelling and redness along a vein that is very tender or even painful to the touch.
- Very high fever, chills or mouth ulcers as a result of infections (lack of white blood cells).
- Severe persistent blurred vision.
- Inflammation of tendon or tendons (connective tissues that connect muscles to bones).

Rare side effects (effects that appear in 1-10 out of 10,000 users):

- Difficulty breathing, chest pain, fainting, rapid heartbeat, blue tinged skin, or sudden pain in an arm, leg, or foot (signs that a blood clot may have formed).
- Rupture of a tendon (connective tissues that connect muscles to bones).

In addition, inform the doctor immediately if you suffer from any of the following symptoms during the treatment with **Letrozole Dexcel**:

- 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, blisters on lips, eyes, or mouth, skin peeling, fever (signs of skin disorder).

Additional side effects

Very common side effects (effects that appear in more than 1 in 10 users): hot flushes; high cholesterol level (hypercholesterolemia); tiredness (including weakness [generally feeling unwell]); increased sweating; pain in bones and joints (arthralgia). If one or more of these effects is severely affecting you, refer to your doctor.

Common side effects (effects that appear in 1-10 out of 100 users): skin rash; headache; dizziness; gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhea; increased appetite or loss of appetite; muscle pain; thinning or wasting of the bones (osteoporosis) that leads to bone fractures in some cases (see also in section 2 'Tests and follow-up'); swelling of the arms, hands, feet, and ankles (edema); depression; weight gain; hair loss; a 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 effects is severely affecting you, refer to your doctor.
Uncommon side effects (effects that appear in 1-10 out of 1,000 users): nervous system 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 of touch; eye impairment

such as blurred vision, eye irritation; skin disorder such as itching (urticaria); vaginal discharge or vaginal dryness; breast pain; fever; thirst, an impaired sense of taste, dry mouth; dryness of mucus membranes; weight loss; urinary tract infection, increased frequency of urination; cough; increase in enzyme levels; yellowing of the skin and eyes; high levels of bilirubin in the blood (a breakdown product of red blood cells).

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

Trigger finger, a condition in which the finger or thumb is frozen in a bent position.

If one or more of these side effects is severely affecting you, refer to your doctor.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link

"דיווח על תופעות לוואי בקביעות" תחת "הודעה" which can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store at a temperature above 30°C. Store in the original package to protect from moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, microcrystalline cellulose, maize starch, sodium starch glycolate, hydroxypropylmethylcellulose, talc, magnesium stearate, titanium dioxide (E 171), hydroxypropylcellulose, cotton seed oil, iron oxide yellow (E 172), iron oxide red (E 172).

What the medicine looks like and what the package contains:

Yellow, round, coated, biconvex tablets. Approved package sizes: 28, 30 tablets. Not all package sizes may be marketed.

Manufacturer and address: Haupt Pharma Münster GmbH, Münster, Germany Revised in March 2020.

Drug registration number at the national drug registry of the Ministry of Health: 145 49 33275 00

Letrozole Dexcel 2.5 Tab PIL PB0520-06

Registration holder:

Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel