



Patient package insert according to Pharmacists' Regulations (Preparations) - 1986

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

LYRICA 25, 50, 75, 100, 150, 200, 225, 300, Capsules

Each capsule contains Pregabalin 25, 50, 75, 100, 150, 200, 225, 300 mg, respectively.

Inactive ingredients and allergens in the medicine - see section 6 "Additional Information" and in section 2 under "Important information about some of the ingredients of the medicine".

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is the same as yours.

This medicine is not intended for treatment of children and adolescents under 18 years of age.

1. What is the medicine intended for?

For treatment of neuropathic (neural) pain in adults, for treatment of fibromyalgia and for treatment of generalised anxiety disorder in adults.

Therapeutic group:

A gamma-aminobutyric acid analog.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (Pregabalin), or to any of the other ingredients this medicine contains (listed in section 6).

Special warnings regarding the use of the medicine

Refer to your doctor before taking Lyrica.

- Some patients taking **Lyrica** have reported allergic effects. These effects include swelling of the face, lips, tongue and throat, as well as diffuse skin rash. If you experience one or more of these effects, refer to a doctor immediately.
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with **Lyrica**. Stop using the medicine and refer to a doctor immediately if you experience one or more of the symptoms related to these serious skin reactions described in section 4.
- The medicine may cause dizziness and somnolence, such that elderly patients taking the medicine are at increased risk of falls and injuries. Exercise caution until you become accustomed to the effect of the medicine on you.
- The medicine may cause blurring or loss of vision, or other changes in eyesight, most of which are transient - inform the doctor immediately of any change in your vision.
- In some patients with diabetes, who gain weight while taking the medicine, the dosage of medicines for lowering the blood sugar level may have to be adjusted.

- Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking other medicines to treat pain and spasticity, which have side effects similar to those of **Lyrice** and their severity may increase when these are taken together.
- Heart failure has been reported in a number of patients who took **Lyrice**, mostly in elderly patients with cardiovascular diseases. **Before starting the use of the medicine, inform the doctor if you suffer, or suffered in the past, from a heart disease.**
- A few cases of kidney failure associated with treatment with **Lyrice** have been reported. If you notice decreased urination during the treatment with the medicine, inform the doctor, as discontinuation of treatment with the medicine may bring an improvement.
- Some patients who were treated with antiepileptic medicines such as **Lyrice** have had thoughts of harming or killing themselves or shown suicidal behavior. In case of onset of such thoughts or behavior at any stage, refer to the doctor immediately.
- Combination of **Lyrice** with other medicines (e.g., certain types of analgesics) which might cause constipation, may cause gastrointestinal problems (e.g., constipation, blocked or paralyzed bowel). Inform the doctor if you are suffering from constipation, especially if you are prone to constipation.
- Before starting this medicine, inform your doctor if you are or have previously been dependent on or addicted to alcoholic beverages, drugs or any medicines. In this case, you may have a greater risk of becoming dependent on **Lyrice**.
- Convulsions may occur during treatment with the medicine or immediately after its discontinuation – inform the doctor immediately if you are suffering from convulsions.
- Reduced brain functioning (encephalopathy) has been reported in a number of patients with other underlying ailments. Inform the doctor if you are aware of any serious medical conditions, including liver or kidney diseases.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, or you are older than 65, your doctor may prescribe you a different dosing regimen. Consult your doctor if you experience difficulty breathing or shallow breaths.

Dependence

Some people may become dependent on **Lyrice** (a need to keep taking the medicine). They may have withdrawal effects when they stop using **Lyrice** (see section 3, “How to use this medicine?” and “If you stop taking the medicine”). If you have concerns that you may become dependent on **Lyrice**, it is important that you consult your doctor.

If you notice any of the following signs while taking **Lyrice**, it could be a sign that you have become dependent:

- You need to take the medicine for longer than prescribed for you
- You feel you need to take more than the dose prescribed for you
- You are using the medicine for reasons other than those for which it was prescribed
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, contact your doctor to discuss the best treatment for you, including when you should stop taking the medicine and how to do this safely.

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:

Lyrica and certain other medicines may have mutual influences on activity.

If **Lyrica** is taken with certain medicines which have sedative effects (including opioids), **Lyrica** may potentiate these effects, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if **Lyrica** is taken together with:

Oxycodone – an analgesic

Lorazepam – a medicine for the treatment of anxiety

Alcohol

Lyrica may be taken with oral contraceptives.

Use of the medicine and food

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption

Do not consume alcohol during the treatment with the medicine.

Pregnancy, breastfeeding and fertility

Do not use **Lyrica** during pregnancy or when breastfeeding, unless the doctor has instructed you to do so after consulting with him. Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. In a study reviewing data from women in Nordic countries who took pregabalin in the first 3 months of pregnancy, 6 in 100 babies had such birth defects. This compares to 4 in 100 babies born to women not treated with pregabalin in the study. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Women who may become pregnant during the treatment with the medicine must use effective contraceptive measures.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor or pharmacist before using this medicine.

Driving and using machines

Do not drive or operate dangerous machinery until you know how the medicine affects you, since use of this medicine may cause dizziness, drowsiness or decreased concentration.

Important information about some of the ingredients of the medicine

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

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

3. How should you use the 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 manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

Do not exceed the recommended dose.

Method of administration

Swallow the capsule whole. Do not open and disperse the contents of the capsule, since such forms of administration have not been tested. Swallow the medicine with water.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. You may feel sleepy, confused, agitated or restless as a result of taking an overdose of **Lyricea**. In addition, there have been reports of fits (convulsions) and unconsciousness (coma).

If you forgot to take this medicine at the scheduled time

It is important to take the medicine every day at a set time. If you forget to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

If you stop taking the medicine

If a decision is made to discontinue treatment, your doctor will tell you how to do it. Discontinuation of treatment with the medicine must be gradual, over a period of at least one week.

After stopping treatment with the medicine (whether short or long-term treatment), you may experience certain symptoms called withdrawal symptoms. These symptoms include insomnia, headaches, nausea, anxiety, diarrhea, flu-like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating and dizziness. These effects may be more common and more severe if the medicine has been taken for a longer period of time. If you experience withdrawal symptoms, you should contact your doctor.

Do not take medicines in the dark! Check the label and 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 **Lyricea** 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.

Refer to a doctor immediately if you suffer from swelling of the face or tongue or a severe skin reaction (the skin reddens and becomes covered with blisters or peels).

Very common side effects (effects that occur in more than 1 in ten users):

Dizziness, drowsiness, headaches.

Common side effects (effects that occur in 1-10 out of 100 users):

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Concentration or memory impairment, loss of memory, clumsiness, tremor, speech disturbance, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.

- Blurred vision, double vision.
- Vertigo, balance disorders, falls.
- Dry mouth, constipation, vomiting, flatulence, diarrhea, nausea, swollen abdomen.
- Erection problems.
- Swelling of the body including the extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramps, joint pain, back and limb pains.
- Sore throat.

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

- Loss of appetite, weight loss, decreased blood sugar level, increased blood sugar level.
- Change in self-perception, restlessness, depression, anxiety, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attacks, apathy, aggression, elevated mood, mental impairment, difficulty with thinking, increase in sexual interest, problems with sexual functioning, including inability to achieve a sexual climax, delayed ejaculation.
- Vision changes including loss of peripheral vision, unusual eye movement, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, skin sensitivity, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling or pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low or high blood pressure, changes in heart beat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numbness around the mouth.
- Sweating, rash, chills, fever.
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- Breast pain.
- Difficulty with or painful urination, incontinence.
- Weakness, thirst, chest tightness.
- Changes in blood and liver function tests (increased blood creatine phosphokinase, increased liver enzymes, decreased blood platelets, neutropenia, increased blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Cold hands and feet.

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

- Abnormal sense of smell, swinging vision, change in depth perception, visual brightness, vision loss.
- Dilated pupils, crossed eyes.
- Cold sweat, irritation of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slower or reduced movement of the body.
- Difficulty with writing.
- Edema in the abdominal area.

- Fluid in the lungs.
- Convulsions.
- Changes in ECG which correspond to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in men.
- Menstrual period disturbances.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count in blood test.
- Abnormal behavior, suicidal behavior, suicidal thoughts.
- Allergic reactions that may be manifested by breathing difficulties, inflammation of the eyes (keratitis) and serious skin reactions characterized by reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Jaundice (yellowing of the skin and whites of the eyes).
- Parkinsonism, that is symptoms resembling Parkinson's disease such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Liver failure.
- Hepatitis (inflammation of the liver).

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

- Becoming dependent on **Lyrica**

After stopping treatment (short or long-term) with **Lyrica**, you may experience certain symptoms called withdrawal symptoms (see Section 3 "**If you stop taking the medicine**").

Certain side effects, such as sleepiness, may be more common, because patients with spinal cord injury may be taking additional medicines to treat pain and spasticity, which have side effects similar to those of **Lyrica** and their severity may increase when these are taken together.

The following side effects have been reported post-marketing: difficulty breathing and shallow breaths.

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

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of Ministry of Health (www.health.gov.il) directing to the online form for reporting side effects or via the 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 (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage Conditions:** Store below 25°C.

6. Additional information

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

Lactose monohydrate, maize starch, talc, gelatin, water, titanium dioxide, sodium lauryl sulphate, silica colloidal anhydrous.

Lyrica 75 mg, 100 mg, 200 mg, 225 mg and 300 mg capsules also contain:

Red iron oxide.

What the medicine looks like and what the package contains:

Lyrica 25 mg: a white capsule with the word "VTRS" imprinted on one side and "PGN 25" on the other side.

Lyrica 50 mg: a white capsule with a black stripe, with the word "VTRS" imprinted on one side and "PGN 50" on the other side.

Lyrica 75 mg: a white-orange capsule with the word "VTRS" imprinted on one side and "PGN 75" on the other side.

Lyrica 100 mg: an orange capsule with the word "VTRS" imprinted on one side and "PGN 100" on the other side.

Lyrica 150 mg: a white capsule with the word "VTRS" imprinted on one side and "PGN 150" on the other side.

Lyrica 200 mg: a light orange capsule with the word "VTRS" imprinted on one side and "PGN 200" on the other side.

Lyrica 225 mg: a white-light orange capsule with the word "VTRS" imprinted on one side and "PGN 225" on the other side.

Lyrica 300 mg: a white-orange capsule with the word "VTRS" imprinted on one side and "PGN 300" on the other side.

Approved package sizes: 14, 21, 28, 56, 84, 100, 112 capsules.

Not all package sizes may be marketed.

Revised in December 2024 according to MOH guidelines.

Drug registration numbers at the national drug registry of the Ministry of Health:

Lyrica 25 mg: 132.97.31185.00

Lyrica 50 mg: 132.98.31186.00

Lyrica 75 mg: 132.99.31187.00

Lyrica 100 mg: 133.01.31188.00

Lyrica 150 mg: 133.02.31189.00

Lyrica 200 mg: 133.03.31190.00

Lyrica 225 mg: 148.19.33471.00

Lyrica 300 mg: 133.04.31191.00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel.