PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

LYRICA® 25 mg
LYRICA® 50 mg
LYRICA® 75 mg
LYRICA® 100 mg
LYRICA® 150 mg
LYRICA® 200 mg
LYRICA® 225 mg
LYRICA® 300 mg

Capsules

Active ingredient:

Pregabalin 25, 50, 75, 100, 150, 200, 225, 300 mg

Inactive ingredients and allergens: see section 2 under "Important information regarding some of the ingredients of the medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others; it may harm them even if it seems to you that their medical condition is similar to 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 THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (detailed in section 6).

Special warnings regarding use of the medicine

Refer to your doctor before taking the medicine.

- 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.

- The medicine may cause dizziness and somnolence, such that elderly patients taking the preparation 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 preparation, 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 Lyrica and their severity may increase when these are taken together.
- Heart failure has been reported in a number of patients who took Lyrica, mostly in elderly patients with cardiovascular diseases. **Before starting use of the medicine, inform the doctor if you are suffering, or have suffered in the past, from a heart disease.**
- A few cases of kidney failure associated with treatment with Lyrica 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.
- Suicidal thoughts or suicidal behavior have been reported in a small number of patients who were treated with antiepileptic medicines such as Lyrica. You and your family members should pay attention to any changes in mood and behavior patterns. In case of onset of such thoughts at any stage, refer to the doctor immediately.
- Combination of Lyrica 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 commencing use of the medicine, inform the doctor if you are suffering, or have suffered in the past, from addiction to or dependence on alcoholic beverages, drugs or any medicines. Do not take a higher dosage than that which has been prescribed for you.
- 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.

Drug interactions

If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, 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 treating anxiety

Alcohol

Lyrica may be taken with oral contraceptives.

Use of Lyrica and food

The medicine can be taken without regard to meals.

Use of Lyrica and consumption of alcohol

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.

Consult a doctor or pharmacist before using the medicine if you are pregnant or breastfeeding, if you suspect that you are pregnant or you are planning to become pregnant.

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 regarding some of the ingredients of the medicine

The preparation 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 the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dosage or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose!

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, refer to a doctor immediately or proceed to 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 Lyrica. In addition, there have been reports of fits (convulsions).

If you forget to take this medicine at the required 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 usual time and consult the doctor.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If a decision is made to discontinue treatment, discontinuation of treatment with the medicine must be gradual, over a period of at least one week.

After stopping treatment with the medicine (whether the treatment was short-term or long-term), you may experience: insomnia, headaches, nausea, anxiety, flu-like symptoms, convulsions, nervousness, depression, pain, dizziness, sweating and diarrhea. These effects may be more common and more severe if the medicine has been taken for a longer period of time.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take the medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lyrica 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: occur in more than 1 in 10 people

Dizziness, drowsiness, headaches.

Common side effects: occur in up to 1 in 10 people

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability, clumsiness.
- Concentration or memory impairment, loss of memory, 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: occur in up to 1 in 100 people

- 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, delayed ejaculation.
- Vision changes including loss of peripheral vision, nystagmus, 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: occur in up to 1 in 1,000 people

- 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.
- Allergic reactions (may be manifested by: breathing difficulties, inflammation of the eyes [keratitis] and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- 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: can occur in up to 1 in 10,000 people

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

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 any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the following link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- 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 in order 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) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.

6. FURTHER 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.

The preparation contains lactose monohydrate:

Lyrica 25 mg - 35 mg lactose monohydrate, Lyrica 50 mg - 70 mg lactose monohydrate, Lyrica 75 mg - 8.25 mg lactose monohydrate, Lyrica 100 mg - 11 mg lactose monohydrate, Lyrica 150 mg - 16.5 mg lactose monohydrate, Lyrica 200 mg - 22 mg lactose monohydrate, Lyrica 225 mg - 24.75 mg lactose monohydrate, Lyrica 300 mg - 33 mg lactose monohydrate.

What the medicine looks like and the contents of the package:

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

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

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

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

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

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

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

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

The medicine is available in a package of 14, 21, 28, 56, 84, 100, 112 capsules.

Not all package sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzeliya Pituach 46725.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Lyrica 25 mg:	132.97.31185
Lyrica 50 mg:	132.98.31186
Lyrica 75 mg:	132.99.31187
Lyrica 100 mg:	133.01.31188
Lyrica 150 mg:	133.02.31189
Lyrica 200 mg:	133.03.31190
Lyrica 225 mg:	148.19.33471
Lyrica 300 mg:	133.04.31191

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