GLUE PANEL

Lyrica® 20 mg/mL oral solution pregabalin

PAA217715

FPO 128 - 10 MIL

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GLUE PANEL

Package leaflet: Information for the user

Lyrica® 20 mg/mL oral solution

pregabalin

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 Lyrica is and what it is used for

Lyrica belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalised Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain: Lyrica is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: Lyrica is used to treat a certain form of epilepsy (partial seizures with or without secondary generalisation-epileptic fits starting on one specific part of the brain) in adults. Your doctor will prescribe Lyrica for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Lyrica in addition to your current treatment. Lyrica is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalised Anxiety Disorder: Lyrica is used to treat Generalised Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

2. What you need to know before you take Lyrica

Do not take Lyrica
if you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions
Talk to your doctor or pharmacist before taking Lyrica.
- Some patients taking Lyrica have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with pregabalin. Stop using pregabalin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- Lyrica has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- Lyrica may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking pregabalin may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to pregabalin and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking Lyrica; these patients were mostly elderly with cardiovascular conditions. **Before taking this medicine you should tell your doctor if you have a history of heart disease**.
- There have been reports of kidney failure in some patients when taking Lyrica. If while taking Lyrica you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- Some patients being treated with anti-epileptics such as Lyrica have had thoughts of harming or killing themselves or shown suicidal behaviour. If at any time you have these thoughts or show such behaviour, immediately contact your doctor.
- When Lyrica is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs; it may mean you have a greater risk of becoming dependent on Lyrica.
- There have been reports of convulsions when taking Lyrica or shortly after stopping Lyrica. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking Lyrica when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.
- 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. Contact your doctor if you experience trouble breathing or shallow breaths.

Dependence

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

If you notice any of the following signs whilst taking Lyrica, it could be a sign that you have become dependent:
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to take more than the recommended dose
- You are using the medicine for reasons other than 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, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to do this safely.

Children and adolescents
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

Other medicines and Lyrica
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Lyrica and certain other medicines may influence each other (interaction). When taken with certain other 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 medicines containing:

Oxycodone – (used as a pain-killer)
Lorazepam – (used for treating anxiety)
Alcohol
Lyrica may be taken with oral contraceptives.

Lyrica with food, drink and alcohol
Lyrica may be taken with or without food.

It is advised not to drink alcohol while taking Lyrica

Pregnancy and breast-feeding
Lyrica should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. 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 babies in every 100 had such birth defects. This compares to 4 babies in every 100 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.

Effective contraception must be used by women of childbearing potential. 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 this medicine.

Driving and using machines
Lyrica may produce dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Lyrica contains methyl parahydroxybenzoate and propyl parahydroxybenzoate
Lyrica oral solution contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

Lyrica contains ethanol
Lyrica oral solution contains small amounts of ethanol (alcohol), less than 100 mg/mL.

Lyrica contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per maximum daily dose of 600 mg (30 mL), that is to say essentially ‘sodium-free’.

3. How to take Lyrica

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not take more medicine than prescribed.

Your doctor will determine what dose is appropriate for you.

Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:
- Take the solution as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg (7.5 mL) and 600 mg (30 mL) each day.
- Your doctor will tell you to take Lyrica either twice or three times a day. For twice a day take Lyrica once in the morning and once in the evening, at about the same time each day. For three times a day take Lyrica once in the morning, once in the afternoon and once in the evening, at about the same time each day.

If you have the impression that the effect of Lyrica is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly patient (over 65 years of age), you should take Lyrica normally except if you have problems with your kidneys.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Continue taking Lyrica until your doctor tells you to stop.

Administration:

Instructions for use

Lyrica is for oral use only.

1. Open the bottle: Press downward on the cap and turn it counter-clockwise (Figure 1).
2. **First time use only:** A Press-In Bottle Adapter (PIBA) is provided with the oral syringe. This is the device that gets inserted into the neck of the bottle to make it easier to withdraw the solution using the oral syringe. If the PIBA is not already in place, remove the PIBA and 5 mL oral syringe from the plastic overwrap. With the bottle on a flat surface, insert the PIBA into the bottle neck while keeping the PIBA’s flat surface facing up and pressing on it (Figure 2).
3. Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air. Attach the syringe to the PIBA with a slight twisting motion (Figure 3).
4. Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (mL) prescribed by your doctor (Figure 4). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
5. Return the bottle to an upright position with the syringe still in the PIBA/bottle (Figure 5).
6. Remove the syringe from the bottle/PIBA (Figure 6).
7. Empty the contents of the syringe directly into mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7).

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MA No.	PLGB 50622/0070	Client Market	United Kingdom				
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Packing Site/Printer	Pfizer Manufacturing Kalamazoo (Kalamazoo - US)						
Sign-offs	Project # 18645, SKU F000048797, PAR-2023-0008511						

V3 MAY 2023

Note: Steps 4-7 may need to be repeated up to three times to obtain the total dose (Table 1).

[For example, a 150 mg (7.5 mL) dose will require two withdrawals from the bottle to achieve the entire dose. Using the oral syringe, first withdraw 5 mL and empty contents of syringe directly into the mouth, then refill the oral syringe with 2.5 mL and empty the remaining contents into the mouth.]

8. Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).
9. Replace the cap on the bottle (leaving the PIBA in place in the bottle neck) (Figure 9).

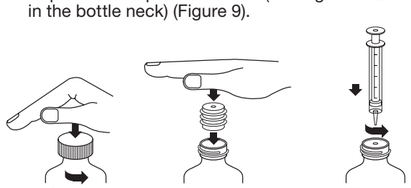
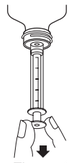


Figure 1

Figure 2

Figure 3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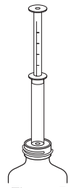
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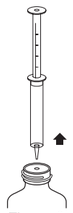
Figure 6


Figure 7


Figure 8

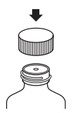
Figure 9

Table 1. Oral Syringe Withdrawals to Deliver Prescribed Dose of Lyrica

Lyrica Dose (mg)	Total Solution Volume (mL)	First Syringe Withdrawal (mL)	Second Syringe Withdrawal (mL)	Third Syringe Withdrawal (mL)
25	1.25	1.25	Not required	Not required
50	2.5	2.5	Not required	Not required
75	3.75	3.75	Not required	Not required
100	5	5	Not required	Not required
150	7.5	5	2.5	Not required
200	10	5	5	Not required
225	11.25	5	5	1.25
300	15	5	5	5

If you take more Lyrica than you should
Call your doctor or go to the nearest hospital emergency unit immediately. Take your box or bottle of Lyrica oral solution with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Lyrica than you should. Fits and unconsciousness (coma) have also been reported.

If you forget to take Lyrica
It is important to take your Lyrica oral solution regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lyrica
Do not suddenly stop taking Lyrica. If you want to stop taking Lyrica, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped it should be done gradually over a minimum of 1 week. After stopping a short or long-term treatment with Lyrica, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu like symptoms, convulsions, nervousness, depression, thoughts of harming or killing yourself, pain, sweating, and dizziness. These effects may occur more commonly or severely if you have been taking Lyrica for a longer period of time. If you experience withdrawal effects, you should contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

Dizziness, drowsiness, headache.

Common: may affect up to 1 in 10 people

- Increased appetite.
- Feeling of elation, confusion, disorientation, decrease in sexual interest, irritability.
- Disturbance in attention, clumsiness, memory impairment, loss of memory, tremor, difficulty with speaking, tingling feeling, numbness, sedation, lethargy, insomnia, fatigue, feeling abnormal.
- Blurred vision, double vision.
- Vertigo, problems with balance, fall.
- Dry mouth, constipation, vomiting, flatulence, diarrhoea, nausea, swollen abdomen.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.
- Muscle cramp, joint pain, back pain, pain in limb.
- Sore throat.

Uncommon: may affect up to 1 in 100 people

- Loss of appetite, weight loss, low blood sugar, high blood sugar.
- Change in perception of self, restlessness, depression, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, panic attack, 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.
- Changes in eyesight, unusual eye movement, changes in vision including tunnel vision, flashes of light, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased consciousness, loss of consciousness, fainting, increased sensitivity to noise, feeling unwell.
- Dry eyes, eye swelling, eye pain, weak eyes, watery eyes, eye irritation.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure, changes in heart beat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numb around 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 test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, platelet count decreased, neutropaenia, increase in blood creatinine, decrease in blood potassium).
- Hypersensitivity, swollen face, itchiness, hives, runny nose, nose bleed, cough, snoring.
- Painful menstrual periods.
- Coldness of hands and feet.

Rare: may affect up to 1 in 1,000 people

- Abnormal sense of smell, swinging vision, altered perception of depth, visual brightness, vision loss.
- Dilated pupils, cross eyes.
- Cold sweat, tightness of the throat, swollen tongue.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slow or reduced movement of the body.
- Difficulty with writing properly.
- Increased fluid in the abdomen.
- Fluid in the lungs.
- Convulsions.
- Changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances.
- Muscle damage.
- Breast discharge, abnormal breast growth, breast growth in males.
- Interrupted menstrual periods.
- Kidney failure, reduced urine volume, urinary retention.
- Decrease in white blood cell count.
- Inappropriate behaviour, suicidal behaviour, suicidal thoughts.
- Allergic reactions which may include difficulty breathing, 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 eyes).
- Parkinsonism, that is symptoms resembling Parkinson's disease; such as tremor, bradykinesia (decreased ability to move), and rigidity (muscle stiffness).

Very rare: may affect up to 1 in 10,000 people

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

Not known: frequency cannot be estimated from the available data

- Becoming dependent on Lyrica ('drug dependence').

After stopping a short or long-term treatment with Lyrica, you need to know that you may experience certain side effects, so-called withdrawal effects (see "If you stop taking Lyrica").

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel, you should seek immediate medical advice.

Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Lyrica and the severity of these effects may be increased when taken together.

The following adverse reaction has been reported in the postmarketing experience: Trouble breathing, shallow breaths.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lyrica

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 or bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Lyrica contains

The active substance is pregabalin. Each mL contains 20 mg of pregabalin.

The other ingredients are: methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium dihydrogen phosphate, anhydrous, disodium phosphate, anhydrous (E339), sucralose (E955), artificial strawberry flavour (contains small amounts of ethanol (alcohol), purified water.

What Lyrica looks like and contents of the pack

Lyrica 20 mg/mL oral solution is a clear colourless solution in a white bottle containing 473 mL of oral solution, in a cardboard carton. The carton also contains, in a clear polyethylene wrap, a graduated 5 mL oral syringe and a press-in bottle adapter (PIBA).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Upjohn UK Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom

Manufacturer:
Mylan Hungary Kft., Mylan utca 1, Komárom 2900, Hungary

This leaflet was last revised in: 12/2023.

REF: LY 33_0

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Sign-offs	Project # 18645, SKU F000048797, PAR-2023-0008511						
							V3 MAY 2023