Package leaflet: Information for the user

Lyrica 25 mg hard capsules,
Lyrica 50 mg hard capsules,
Lyrica 75 mg hard capsules,
Lyrica 100 mg hard capsules,
Lyrica 150 mg hard capsules,
Lyrica 200 mg hard capsules,
Lyrica 225 mg hard capsules,
Lyrica 300 mg hard capsules
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) 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.

- 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.

- A small number of people being treated with anti-epileptics such as Lyrica have had thoughts of harming or killing themselves. If at any time you have these thoughts, 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 you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.

- 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.

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, Lyrica may potentiate the side effects seen with these medicines, including respiratory failure and coma. 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 capsules 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. Effective contraception must be used by women of child-bearing 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 lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

Your doctor will determine what dose is appropriate for you.

Lyrica is for oral use only.

Peripheral and central neuropathic pain, epilepsy or Generalised Anxiety Disorder:
- Take the number of capsules as instructed by your doctor.
- The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg 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.

Swallow the capsule whole with water.

Continue taking Lyrica until your doctor tells you to stop.

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 capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Lyrica than you should. Fits have also been reported.

If you forget to take Lyrica
It is important to take your Lyrica capsules 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 stop taking Lyrica unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term Lyrica treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking Lyrica for a longer period of time.

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.
- Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain).
- Jaundice (yellowing of the skin and eyes).

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

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

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 Pregabalin and the severity of these effects may be increased when taken together.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta
ADR Reporting
The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GZR-1368 Gzira.
Website: www.medicinesauthority.gov.mt
E-mail: postlicensing.medicinesauthority@gov.mt

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 or household waste. 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 hard capsule contains either 25 mg**,** 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg pregabalin.

The other ingredients are: lactose monohydrate, maize starch, talc, gelatine, titanium dioxide (E171), sodium laurilsulphate, anhydrous colloidal silica, black ink, (which contains shellac, black iron oxide (E172), propylene glycol, potassium hydroxide) and water.

The 75 mg, 100 mg, 200 mg, 225 mg and 300 mg capsules also contain red iron oxide (E172).

What Lyrica looks like and contents of the pack	
25 mg capsules	White hard capsules, with “Pfizer” marked on the cap and “PGN 25” on the body.
50 mg capsules	White hard capsules, with “Pfizer” marked on the cap and “PGN 50”on the body. The capsule body is marked with a black band.
75 mg capsules	White and orange hard capsules with “Pfizer” marked on the cap and “PGN 75” on the body.
100 mg capsules	Orange hard capsules, with “Pfizer” marked on the cap and “PGN 100” on the body.
150 mg capsules	White hard capsules, with “Pfizer” marked on the cap and “PGN 150” on the body.
200 mg capsules	Light orange hard capsules, with “Pfizer” marked on the cap and “PGN 200” on the body.
225 mg capsules	White and light orange hard capsules, with “Pfizer” marked on the cap and “PGN 225” on the body.
300 mg capsules	White and orange hard capsules, with “Pfizer” marked on the cap and “PGN 300” on the body.

Lyrica is available in eight pack sizes made of PVC with an aluminium foil backing: a 14 capsules pack containing 1 blister strip, a 21 capsules pack containing 1 blister strip, a 56 capsules pack containing 4 blister strips, a 70 capsules pack containing 5 blister strips, a 84 capsules pack containing 4 blister strips, a 100 capsules pack containing 10 blister strips, a 112 capsules pack containing 8 blister strips and 100 x 1 capsules as perforated unit dose blisters.

In addition, Lyrica is available in an HDPE bottle containing 200 capsules for the 25 mg, 75 mg, 150 mg and 300 mg strengths**.**

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium.

Manufacturer:
Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1, 79090 Freiburg, Germany.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Pfizer Healthcare Ireland

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Tel: +44 (0)1304 616161

United Kingdom
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Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu