PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

LYRICA® 25 mg Capsules

LYRICA® 75 mg Capsules

LYRICA® 150 mg Capsules

Pregabalin

Contains sugar (lactose monohydrate).

Each LYRICA 25 mg capsule contains 35 mg lactose monohydrate.

Each LYRICA 75 mg capsule contains 8,25 mg lactose monohydrate.

Each LYRICA 150 mg capsule contains 16,5 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking LYRICA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LYRICA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LYRICA is and what it is used for

LYRICA is used in adults to treat long lasting pain caused by damage to the nerves, as in diabetes mellitus and shingles (Herpes zoster). Pain from damaged nerves is called neuropathic pain. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles, etc. If you have diabetes, the pain can be in your arms, hands, fingers, legs, feet or toes. If you have shingles, the pain is in the area of the rash.

2. What you need to know before you take LYRICA

Do not take LYRICA

- If you are hypersensitive (allergic) to pregabalin or any of the other ingredients of LYRICA (listed in section 6).

Warnings and precautions

Take special care with LYRICA:

- Some patients with diabetes who gain weight while taking LYRICA may need an alteration in their diabetic medicines.
- 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 hives or nettle rash. Should you experience any of these reactions, you should contact your doctor immediately.
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with LYRICA. Stop using LYRICA 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 drowsiness, 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.
- There have been reports of breathing difficulties. If you have nervous system disorders, respiratory disorders, renal impairment, using other medicines that may depress your central nervous system 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.

- Some patients being treated with medicines such as LYRICA have had thoughts of harming or killing themselves or shown suicidal behaviour. If at any time you have these thoughts or shown such behaviour, immediately contact your doctor, as your treatment with LYRICA may need to be stopped.
- When taken with certain other medicines which have sedative effects such as opioids, LYRICA may potentiate these effects and could lead to respiratory failure, coma and death.
- Some people may become dependent on LYRICA (a need to keep taking the medicine). Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs, or if you have any mental health disorders; it may mean you have a greater risk of becoming dependent on 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 doctor.
  - 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.
- You may experience withdrawal effects when you stop using LYRICA (see section 3).
- If you are suffering from or have ever suffered from any kidney conditions. If so, your doctor may prescribe a lower dose of LYRICA.
- If you have heart problems including heart failure.
- If you are pregnant, trying to become pregnant or breastfeeding (see Pregnancy and breastfeeding).

Children and adolescents

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

Other medicines and LYRICA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- LYRICA may be taken with birth control pills.
- Any narcotic pain medicine (such as oxycodone), tranquilizers or medicines for anxiety (such as lorazepam) may increase the chance of dizziness and sleepiness when taken with LYRICA.
- 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. You may also be at risk if you have ever abused or been dependent on alcohol, prescription medicines or illegal drugs.
- When LYRICA is taken with other medicines that may cause constipation (such as opioids), 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.

LYRICA with food and alcohol

- LYRICA capsules may be taken with or without food (see section 3).
- The effects of alcohol consumption may be increased if you are taking LYRICA.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

LYRICA should not be taken during pregnancy, unless told otherwise by your doctor. Effective contraception must be used by women of childbearing age. Contact your doctor immediately if you become pregnant while taking LYRICA.

Breastfeeding

LYRICA is excreted into breast milk. The effect of LYRICA on newborns/infants is not known. LYRICA should not be taken if you are breastfeeding a baby. Ask your doctor or pharmacist for advice before

taking any medicine whilst breastfeeding.

Driving and using machines

It is not always possible to predict to what extent LYRICA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LYRICA affects them.

LYRICA frequently produces dizziness, drowsiness and tiredness. Head and body injuries and road traffic incidents have also been reported in patients treated with LYRICA. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether LYRICA affects your ability to perform these activities.

LYRICA contains lactose

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

Do not share medicines prescribed for you with any other person.

Always take LYRICA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is between 150 mg and 300 mg each day. Your doctor will determine what dose is appropriate for you.

Take the number of capsules as your doctor has instructed you.

LYRICA must be taken twice a day, once in the morning and once in the evening, at about the same time each day. LYRICA may be taken with or without food. For example, for a daily dose of 150 mg, you must take one 75 mg capsule in the morning and one 75 mg capsule in the evening.

Swallow the capsule whole with plenty of water.

Continue taking LYRICA until your doctor tells you to stop.

Your doctor will tell you how long your treatment with LYRICA will last. If you have the impression that the effect of LYRICA is too strong or too weak, tell your doctor or pharmacist.

If you take more LYRICA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest

hospital or poison centre. Take your box of LYRICA capsules with you. You may experience mood swings, drowsiness or sleepiness, confusion, depression, agitation or restlessness as a result of taking more LYRICA than you should. Cases of coma have also been reported.

If you forget to take LYRICA

It is important to take LYRICA 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. Do not take a double dose to make up for forgotten individual doses.

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, nervousness, depression, thoughts of harming or killing yourself, pain, fits, 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.

4. Possible side effects

LYRICA can have side effects.

Not all side effects reported for LYRICA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LYRICA, please consult your health care provider for advice.

Patients and caregivers should seek medical attention immediately if someone experiences symptoms of respiratory problems, because these can be life-threatening. Symptoms to watch for include:

- Confusion or disorientation.
- Usual dizziness or lightheadedness.
- Extreme sleepiness or lethargy.
- Slowed, shallow or difficult breathing.
- Unresponsiveness, which means a person does not answer or react normally or you cannot wake

them up.

- Bluish-coloured or tinted skin, especially on the lips, fingers and toes.

If the following happens, stop taking LYRICA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swollen face or tongue, or if your skin turns red and starts to blister or peel.

These are very serious side effects. If you have them, you may have had a serious reaction to LYRICA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Very common: may affect more than 1 in 10 people

- Dizziness, drowsiness.

Common: may affect up to 1 in 10 people

- Sore throat and inflammation of the nasal passages.
- Increased appetite.
- Feeling of elation, confusion, decrease in sexual interest, irritability, depression, disorientation, trouble sleeping.
- Clumsiness, disturbance in attention, abnormal coordination, loss of memory, memory impairment, tremor, difficulty with speaking, tingling feeling, numbness, sedation, balance disorder, lethargy.
- Blurred vision, double vision.
- Vertigo.
- Dry mouth, constipation, vomiting, flatulence, swollen abdomen.
- Muscle cramp, joint pain, back pain, pain in limb, spasm in the cervix.
- Fatigue, swelling of the body including extremities, fall, feeling drunk, feeling abnormal, abnormal style of walking.
- Weight gain.

Uncommon: may affect up to 1 in 100 people

- Loss of appetite, low blood sugar.
- Change in perception of self (depersonalisation), problems with sexual functioning including inability to achieve a sexual climax, restlessness, agitation, mood swings, depressed or elevated mood, difficulty finding words, hallucinations, abnormal dreams.

- Problems with memory or speech, unusual eye movement, jerky movements, reduced reflexes, a state of restlessness and anxiety, dizziness on standing, sensitivity or burning of the skin, tremor on movement, fainting.
- Changes in vision including tunnel vision, changes in eyesight, dry eyes, eye swelling, blurred vision, reduced visual sharpness, eye pain, eye strain, seeing flashes of light, increased tearing of the eyes, eye irritation.
- Increased sensitivity to noise.
- Increased or decreased heart rate, changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances.
- Low blood pressure, high blood pressure, flushing, hot flushes, coldness of hands and feet.
- Difficulty breathing, nosebleed, cough, nasal congestion, runny nose, snoring.
- Increased saliva production, heartburn, numbness around the mouth.
- Sweating, rash, hives.
- Muscle twitching, joint swelling, muscle pain, neck pain, muscle stiffness.
- Difficulty with or painful urination, incontinence.
- Difficulties with erection, delayed ejaculation, sexual dysfunction, painful menstrual periods.
- General swelling throughout the body, weakness, thirst, chest tightness, pain, fever, chills.
- Changes in blood and liver test results (abnormally low count of a type of white blood cell called neutrophils, decreased platelet count, increased alanine aminotransferase, increased blood creatinine phosphokinase, increased aspartate aminotransferase, increased blood sugar, decreased blood potassium, weight loss).

Rare: may affect up to 1 in 1 000 people

- Panic attack, uninhibited or inappropriate behaviour, apathy, suicidal behaviour, suicidal thoughts.
- Decreased consciousness, slow or reduced movement of the body, abnormal sense of smell, loss of taste, difficulty with writing properly.
- Dilated pupils, double vision, altered perception of depth, cross eyes, visual brightness.
- Changes in heartbeat.
- Tightness of the throat, dry nose.
- Increased fluid in the abdomen, difficulty in swallowing, inflammation of the pancreas.

- Cold sweat.
- A breakdown of muscle tissue that releases a damaging protein into the blood known as rhabdomyolysis.
- Reduced urine volume, kidney failure.
- Absence of menstrual period, breast pain, breast discharge, breast enlargement.
- Increased blood creatinine, decreased white blood cell count.

Not known: frequency cannot be estimated from the available data

- Slow and shallow breathing.

The following adverse reactions have been reported in the post-marketing experience:

- Swelling of under the skin caused by build-up of fluid, allergic reaction, hypersensitivity.
- Becoming dependent on LYRICA (‘drug dependence’).
- Headache, loss of consciousness, mental impairment, reversible paralysis.
- Inflammation of the eyes (keratitis).
- Heart failure.
- Fluid in the lungs.
- Swollen tongue, diarrhoea, nausea.
- Swollen face, itchiness.
- 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).
- Urinary retention.
- Breast growth in males.
- A general feeling of being unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of

LYRICA.

5. How to store LYRICA

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

Keep the blister in the outer carton.

Protect from light/ moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LYRICA contains

- The active substance is pregabalin. Each capsule contains 25 mg, 75 mg or 150 mg of pregabalin active substance.
- The other ingredients are lactose monohydrate, maize starch and talc.

  The capsule shells contain colloidal anhydrous silica, gelatine, red iron oxide (75 mg capsules), sodium laurilsulfate, titanium dioxide and water.

  The printing ink contains black iron oxide, potassium hydroxide, propylene glycol and shellac.

What LYRICA looks like and content of the pack

LYRICA 25 mg: White, opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 25” on the body with black ink.

LYRICA 75 mg: White (body) and orange (cap), opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 75” on the body with black ink.

LYRICA 150 mg: White, opaque, hard gelatine capsule, marked ”VTRS” on the cap and “PGN 150” on the body with black ink.

Clear PVC/aluminium blisters containing 14, 56 or 100 hard capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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LYRICA 75 mg: A39/2.5/0266

LYRICA 150 mg: A39/2.5/0268

BOTSWANA: S2

LYRICA 25 mg – Reg. No: BOT1101872

LYRICA 75 mg – Reg. No: BOT1101874

LYRICA 150 mg – Reg. No: BOT1101876

NAMIBIA: NS3

LYRICA 25 mg – Reg. No: 08/2.5/0150

LYRICA 75 mg – Reg. No: 08/2.5/0152

LYRICA 150 mg – Reg. No: 08/2.5/0154

ZIMBABWE: PP10

LYRICA 25 mg – Reg. No: 2016/13.1/5304

LYRICA 75 mg – Reg. No: 2016/13.1/5305

LYRICA 150 mg – Reg. No: 2016/13.1/5306