PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LYRICA® 25 mg Capsule

LYRICA® 75 mg Capsule

LYRICA® 150 mg Capsule

Read this leaflet carefully before you start to take LYRICA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- 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.

1. WHAT LYRICA CONTAINS:

The active substance of LYRICA is pregabalin. Each capsule contains 25 mg, 75 mg or 150 mg of pregabalin active substance.

The other ingredients that make up the capsule core are lactose monohydrate, maize starch and talc.

2. WHAT LYRICA 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.

3. BEFORE YOU TAKE LYRICA:

Before being treated with LYRICA, tell your doctor if:

- You have had any allergic reaction to other medicines of this type (e.g. gabapentin or Neurontin)

- You are pregnant, trying to become pregnant or breastfeeding
- You are suffering from or have ever suffered from any kidney conditions. If so, your doctor may prescribe a lower dose of LYRICA
- You have any family problems of galactose intolerance
- You have heart problems including heart failure

Have you ever had an allergic reaction to LYRICA or any of its ingredients?

If you answer yes, do not take this medicine. Tell your doctor or pharmacist at once.

Taking LYRICA with food and drink:

LYRICA capsules may be taken with or without food. The effects of alcohol consumption may be increased if you are taking LYRICA.

Pregnancy and breastfeeding:

Pregnancy:

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

Breastfeeding:

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 machinery:

LYRICA frequently produces dizziness, drowsiness and tiredness. If affected, you should not drive or operate machinery because this could be dangerous to you and others.

The following withdrawal symptoms have been observed in some patients when LYRICA treatment is stopped: difficulty sleeping, headache, nausea and diarrhoea.

Taking other medicines with LYRICA:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LYRICA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice. Before taking any new medication with LYRICA you should check with your doctor. This includes taking medicines available without a prescription (e.g. cough and cold 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.

4. HOW TO TAKE LYRICA:

Always take LYRICA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure how to take the medication.

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.

If you take more LYRICA than you should:

Call your doctor or go to the nearest hospital emergency unit immediately. Take your box of LYRICA capsules with you.

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. Do not take two doses at the same time, to make up for a missed dose.

Effects when treatment with LYRICA is stopped:

Do not stop taking LYRICA unless your doctor tells you to, at which time it should be discontinued gradually.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

LYRICA may cause side effects including:

Allergic reactions (like swelling of the face, mouth, lips, gums, tongue and neck or having trouble

breathing), weight gain, swelling of hands and feet (oedema), dizziness and sleepiness (frequently), eyesight problems (blurry vision), dry mouth, unexplained muscle problems such as muscle pain, soreness or weakness.

6. STORING AND DISPOSING OF LYRICA:

Store LYRICA at room temperature, below 25 °C.

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

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

Return all unused medicine to your pharmacist.

Keep all medicines out of reach and sight of children.

7. PRESENTATION OF LYRICA:

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

8. IDENTIFICATION OF LYRICA:

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.

9. REGISTRATION NUMBER:

LYRICA 25 mg: A39/2.5/0264

LYRICA 75 mg: A39/2.5/0266

LYRICA 150 mg: A39/2.5/0268

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

11. DATE OF PUBLICATION:

02 February 2010

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