PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

[PRODUCT NAME] 25 capsule

[PRODUCT NAME] 75 capsule

[PRODUCT NAME] 150 capsule

Pregabalin

[PRODUCT NAME] 25: Contains sugar: Mannitol 74 mg per capsule

[PRODUCT NAME] 75: Contains sugar: Mannitol 24 mg per capsule

[PRODUCT NAME] 150: Contains sugar: Mannitol 48 mg per capsule

Read all of this leaflet carefully before you start taking [PRODUCT NAME]

- 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.
- **[PRODUCT NAME]** 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 **[PRODUCT NAME]** is and what it is used for
2. What you need to know before you take **[PRODUCT NAME]**
3. How to take **[PRODUCT NAME]**
4. Possible side effects
5. How to store **[PRODUCT NAME]**
6. Contents of the pack and other information

1. What [PRODUCT NAME] is and what it is used for

[PRODUCT NAME] is used to treat peripheral neuropathic pain (long-lasting pain caused by damage to the nerves), due to diabetes or shingles in adults.

2. What you need to know before you take [PRODUCT NAME]

Do not take [PRODUCT NAME]:

- if you are allergic (hypersensitive) to pregabalin or any of the other ingredients of **[PRODUCT NAME]** (listed in section 6).

Warnings and precautions

Take special care with [PRODUCT NAME]:

- If you have diabetes and gain weight while you are taking **[PRODUCT NAME]**, your doctor may need to make a change in your diabetic medicines.
- If you experience an allergic reaction while you are taking **[PRODUCT NAME]**, you must contact your doctor immediately. The symptoms of an allergic reaction include swelling of the face, lips, tongue, and throat, as well as a skin rash.
- If you take **[PRODUCT NAME]** you may experience dizziness, sleepiness, loss of consciousness, confusion, and mental impairment. This could increase the possibility of an accidental injury (fall) if you are an elderly patient. Therefore, you should be careful until you are used to any effect caused by **[PRODUCT NAME]**.
- If you take **[PRODUCT NAME]** you may experience 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.
- If you notice a decrease in passing urine while taking **[PRODUCT NAME]**, you should tell your doctor. It may improve if you stop taking **[PRODUCT NAME]**.

- If you are taking **[PRODUCT NAME]**, or shortly after stopping it, you may experience convulsions (including epilepsy). If this happens, contact your doctor immediately. You may also experience withdrawal symptoms after short-term or long-term treatment with **[PRODUCT NAME]**, which include difficulty in sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, hyperhidrosis and dizziness.
- If you have a history of a heart disease you should tell your doctor. Heart failure has been reported in some patients when they were taking **[PRODUCT NAME]**.
- If you are taking medicines for spinal cord injury, you may experience an increase in certain side effects such as sleepiness, when you are also taking **[PRODUCT NAME]**.
- Some people have had thoughts to harm or kill themselves while taking medicines belonging to the same group as **[PRODUCT NAME]** for the treatment of different conditions. If you have thoughts of harming or killing yourself, at any time when you are taking **[PRODUCT NAME]**, immediately contact your doctor.
- When **[PRODUCT NAME]** 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.
- If you have a history of alcoholism or substance abuse or dependence, you should tell your doctor. If you think you need more **[PRODUCT NAME]** than prescribed, tell your doctor.
- If you have a history of any serious medical conditions you should tell your doctor. There have been reports of reduction in brain function (encephalopathy) in some patients when they were taking **[PRODUCT NAME]**.
- 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. There have been reports of breathing difficulties.

If you are not sure whether any of the above applies to you, ask your pharmacist of your doctor.

Other medicines and [PRODUCT NAME]

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

[PRODUCT NAME] and certain other medicines may influence each other (interaction). When taken with certain other medicines, **[PRODUCT NAME]** 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 **[PRODUCT NAME]** is taken together with medicines containing:

- Oxycodone (for treatment of pain)
- Lorazepam (for treatment of anxiety)
- Alcohol

[PRODUCT NAME] may be taken with oral contraceptives.

[PRODUCT NAME] with food and drink

[PRODUCT NAME] may be taken with or without food.

It is advised not to drink alcohol while you are taking **[PRODUCT NAME]**.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **[PRODUCT NAME]**.

[PRODUCT NAME] should not be taken during pregnancy or when breastfeeding. Effective contraception must be used by women of child-bearing potential.

Driving and using machines

[PRODUCT NAME] may cause dizziness, sleepiness and decreased concentration. Head and body injuries and road traffic incidents have also been reported with **[PRODUCT NAME]**. You should not drive, operate machinery or engage in other potentially hazardous activities until you know whether **[PRODUCT NAME]** affects your ability to perform these activities.

3. How to take [PRODUCT NAME]

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

Always take **[PRODUCT NAME]** exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will determine what dose is appropriate for you.

The usual dose is: 75 mg twice daily, (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.

[PRODUCT NAME] is a long-term treatment and you may need to take it for some time. Your doctor will tell you how long your treatment with **[PRODUCT NAME]** will last.

[PRODUCT NAME] is for oral use only. **[PRODUCT NAME]** is taken orally with or without food. Swallow the capsule whole with water.

If you have the impression that the effect of **[PRODUCT NAME]** is too strong or too weak, tell your doctor or pharmacist.

Children and adolescents:

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore **[PRODUCT NAME]** should not be given to patients in this age group.

Kidney disorders:

Your doctor may prescribe a different dosing schedule and/or dose.

Elderly patients:

If you are an elderly patient (over 65 years of age), you should take **[PRODUCT NAME]** normally except if you have problems with your kidneys. Discuss with your doctor.

If you take more [PRODUCT NAME] than you should

In the event of overdosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison centre. You may feel sleepy, confused, agitated, or restless as a result of taking more **[PRODUCT NAME]** than you should. Fits have also been reported.

If you forget to take [PRODUCT NAME]

It is important to take your **[PRODUCT NAME]** 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 forgotten individual doses.

Effects when treatment with [PRODUCT NAME] is stopped:

Do not stop taking **[PRODUCT NAME]** unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one week.

4. Possible side effects

[PRODUCT NAME] can have side effects.

Not all side effects reported for **[PRODUCT NAME]** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **[PRODUCT NAME]**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **[PRODUCT NAME]** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.
- 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
    - Unusual dizziness or lightheadedness
    - Extreme sleepiness or lethargy
    - Slowed, shallow, or difficult breathing
    - Unresponsiveness, which means a person does not answer or you cannot wake them up
    - Bluish-coloured or tinted skin, especially on the lips, fingers, and toes

These are all very serious side effects. If you have them, you may have had a serious reaction to **[PRODUCT NAME]**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heart disorders including heart failure, heart rhythm disturbances, such as increased heart rate, irregular heartbeat,
- an extremely severe skin reaction with rash, ulcers or blisters on the skin (Stevens-Johnson syndrome),
- inflammation of the eyes (keratitis),
- urinary incontinence, difficulty in passing urine, kidney failure, passing small amounts of urine, urinary retention,
- inflammation of the liver (hepatitis),
- yellowing of the skin and eyes (jaundice).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- inflammation of nasal passages (common cold),
- increased appetite,
- feeling of elation, confusion, irritability, disorientation, sleeplessness, and changes in sexual interest,
- dizziness, sleepiness, headache,
- clumsiness, tremor, difficulty with speaking, forgetfulness, loss of memory, disturbance in attention, numbness or ‘pins and needles’, abnormally decreased sensitivity to stimulation,
- sedation, abnormal style of walking (balance disorder), lack of energy,
- blurred vision, double vision,
- sensation of movement,
- vomiting, nausea, constipation, diarrhoea, feeling bloated, abdominal distension, dry mouth,

- muscle cramp, pain in a joint, back pain, pain in a limb, cervical spasm,
- difficulties with erection,
- swelling of feet and lower legs caused by fluid retention, abnormal manner of walking, falling, feeling drunk, abnormal feeling, tiredness,
- weight gain.

Less frequent:

- reduced numbers of white blood cells which may make you more likely to get infections (neutropaenia),
- loss of appetite, low blood sugar,
- seeing or hearing things that are not there, panic attacks, restlessness, exceeding restlessness, depression, depressed mood, elevated mood, aggression, mood swings, change in perception of self (depersonalisation), difficulty speaking, abnormal dreams, lack of feeling or emotion, loss of inhibition,
- fainting, numbness, contraction of a muscle, loss of consciousness, jerky movements, difficulty of movement, dizziness on standing, tremor on movement, unusual eye movement, decreased consciousness, difficulty with thinking, speech disorder, reduced reflexes, increased sensitiveness of the skin, burning sensation, loss of taste, feeling of bodily discomfort, convulsions, perversion of the sense of smell, partial or complete loss of muscle movement, inability to write coherently, as a symptom of brain disease or damage,
- vision loss, peripheral vision loss, visual disturbance, eye swelling, visual field defect, reduced visual sharpness, eye pain, eye condition that manifests itself through nonspecific symptoms such as fatigue, pain in or around the eyes, the presence of flashes of light, dry eye, watery eyes, eye irritation,
- visual field disturbance, altered visual depth perception, abnormal dilation of the pupil, squinting of eye(s), visual brightness,

- increased sensitivity to sound,
- low blood pressure, high blood pressure, hot flushes, redness of the neck and face, feeling cold,
- shortness of breath, nosebleed, cough, blocked nose, runny nose, snoring, nasal dryness, fluid in the lungs, tightness of the throat,
- heartburn, increased saliva production, numbness around the mouth, abdominal swelling, inflammation of the pancreas, swollen tongue, difficulty in swallowing,
- hives, excessive sweating, itching of the skin, cold sweat,
- joint swelling, pain in a muscle or muscles, muscle twitching, neck pain, muscle stiffness, breakdown of muscle tissue,
- problems with sexual functioning including inability to achieve a sexual climax, increased libido, difficulties with erection, delayed ejaculation, painful menstrual periods, breast pain, absence of menstrual period, breast discharge, breast enlargement, breast enlargement in men,
- generalised swelling caused by fluid retention, swelling of the face, chest tightness, pain, fever, thirst, chills, weakness,
- changes in blood and liver test results (increased blood creatinine phosphokinase, increased alanine amino transferase, increased blood glucose, increased aspartate aminotransferase, decreased platelet count, increased blood creatinine, decreased blood potassium, decreased white blood cell count.

Unknown frequency:

- thoughts of harming or killing one-self.
- Difficulty breathing

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, pharmacist or nurse.

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **[PRODUCT NAME]**.

5. How to store [PRODUCT NAME]

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Keep the container tightly closed.
- Do not use after the expiry date stated on the bottle / carton / label.
- 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 [PRODUCT NAME] contains

The active substance is pregabalin.

[PRODUCT NAME] 25:

Each capsule contains Pregabalin 25 mg.

Contains sugar: Mannitol 74 mg per capsule.

[PRODUCT NAME] 75:

Each capsule contains Pregabalin 75 mg.

Contains sugar: Mannitol 24 mg per capsule.

[PRODUCT NAME] 150:

Each capsule contains Pregabalin 150 mg.

Contains sugar: Mannitol 48 mg per capsule.

The other ingredients are: gelatin, mannitol, sodium lauryl sulphate, talc, titanium dioxide, water, printing ink (Black Iron oxide, Butyl Alcohol, Dehydrated Alcohol, Isopropyl Alcohol, Propylene Glycol, Potassium Hydroxide, Purified water, Shellac, Strong Ammonia solution).

The 75 mg, 150 mg capsules also contain iron oxide red

What [PRODUCT NAME] looks like and contents of the pack

[PRODUCT NAME] 25: Hard gelatin capsules of size '4' with white opaque cap and white opaque body imprinted with 'rbx' on cap and 'PG25' on body containing white to off white powder.

[PRODUCT NAME] 75: Hard gelatin capsules of size '4' with red opaque cap and white opaque body imprinted with 'rbx' on cap and 'PG75' on body containing white to off white powder.

[PRODUCT NAME] 150: Hard gelatin capsules of size '2' with white opaque cap and white opaque body imprinted with 'rbx' on cap and 'PG150' on body containing white to off white powder.

Contents of the pack:

30's or 100's packed in a white opaque HDPE bottle with a child resistance closure (CRC), with an induction seal liner.

10's or 60's packed in a cold form blister pack.

7. Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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Stormill, Ext 1.,

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South Africa

8. This leaflet was last revised in

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9. Registration numbers

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LYBET 150: 47/2.5/1237

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PREGABALIN 75 SUN PHARMA: 48/2.5/0334

PREGABALIN 150 SUN PHARMA: 48/2.5/0335