PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S5

NURIKA 25 (capsule)

NURIKA 50 (capsule)

NURIKA 75 (capsule)

NURIKA 150 (capsule)

Pregabalin

Contains sugar (mannitol).

Read all of this leaflet carefully before you start taking NURIKA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **NURIKA** 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 NURIKA IS AND WHAT IT IS USED FOR:

NURIKA belongs to a group of medicines used to treat neuropathic pain, which is a long lasting pain caused by damage to the nerves, in adults which can be caused by diabetes or shingles (a viral infection which causes a painful skin rash).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NURIKA:

Do not take NURIKA:

- If you are hypersensitive (allergic) to pregabalin or any of the other ingredients of **NURIKA** (**see section 6**).

Warnings and precautions:

Take special care with NURIKA:

- **NURIKA** may cause an allergic reaction. Please inform your doctor immediately if you experience any of the following symptoms: swelling of the face, lips, tongue, and throat, as well as a skin rash.
- **NURIKA** may cause dizziness and drowsiness which can cause accidental falls particularly in the elderly. **NURIKA** can also cause loss of consciousness, confusion and mental impairment. Therefore care should be taken until you know how **NURIKA** affects you.
- Please inform your doctor if you are taking any anti-depressant medicines, since they may cause breathing problems if taken with **NURIKA**.
- When treatment with **NURIKA** is stopped withdrawal symptoms may occur with symptoms such as inability to sleep, headache, nausea (feeling sick), anxiety, flu symptoms, nervousness, depression, pain, fits (seizures), increased sweating and dizziness. Please inform your doctor if you experience any of these symptoms.
- If you suffer from any kidney disease or kidney failure or if while taking **NURIKA** you notice decreased urination, you should notify your doctor.
- Please inform your doctor if you have any heart problems such as congestive heart failure, especially if you are elderly.
- Please inform your doctor if you have diabetes and you gain weight while taking **NURIKA**, since the dose of your diabetic medicines may need to be adjusted.
- **NURIKA** may cause blurring or loss of vision, or temporary changes in your eyesight. You should tell your doctor immediately if you experience any changes in your vision.
- If you are taking **NURIKA** due to a spinal cord injury, side effects such as drowsiness may be increased

(see **section 4 - POSSIBLE SIDE EFFECTS**). This may be caused by other medicines needed to treat this conditon which may have similar side effects as **NURIKA**. If any of these apply to you, your doctor may need to monitor you more closely while you are taking **NURIKA**.

- If you develop thoughts of harming or killing yourself while taking **NURIKA** contact your doctor immediately.
- Please inform your doctor if you are taking other medicines which can cause constipation such as pain-relieving medicines containing codeine or morphine, since constipation can occur with **NURIKA**, especially in females and the elderly.
- Before you take **NURIKA** you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence problems.
- Before you take **NURIKA** please tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease which can cause a brain condition known as encephalopathy.
- There have been reports of breathing difficulties with **NURIKA**. If you have nervous system disorders, respiratory (breathing) disorders, renal (kidney) impairment, or you are older than 65, your doctor may prescribe a different dosing regimen for you. Contact your doctor if you experience trouble breathing or shallow breaths.

Other medicines and NURIKA:

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

NURIKA may increase the side effects (such as impaired concentration and loss of co-ordination) of the following medicines:

- oxycodone (strong pain medicine)
- lorazepam (medicine used to treat anxiety).

The use of **NURIKA** with alcohol may further impair your co-ordination, therefore the consumption of alcohol while you are taking **NURIKA** is not advised.

Taking NURIKA with food and drink:

NURIKA may be taken with or without food.

You should avoid alcohol while taking **NURIKA** (see **Other medicines with NURIKA**).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NURIKA.

Pregnancy:

NURIKA should not be used during pregnancy since safety and efficacy has not been established, therefore effective contraception must be used in women of childbearing potential.

Breastfeeding:

NURIKA is excreted in breast milk therefore, breastfeeding is not recommended, since the effects on newborns/infants are unknown.

Driving and using machines:

NURIKA may cause dizziness, drowsiness, impaired concentration or blurred vision. Therefore, you should not engage in activities such as driving or operating machinery until you know how **NURIKA** affects you.

NURIKA contains mannitol:

NURIKA contains mannitol and may have a laxative effect.

3. HOW TO TAKE NURIKA:

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

Always take **NURIKA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- Your doctor will determine the appropriate dose according to your specific needs.
- **NURIKA** is for oral use and can be taken with or without food.
- Take the capsules as instructed by your doctor. Swallow the capsule whole with water.
- Your doctor may adjust your dose after 3 to 7 days depending on your condition.

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

If you take more NURIKA than you should:

You may feel sleepy, confused, depressed, agitated, restless or get fits or collapse as a result of taking more **NURIKA** than you should.

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

If you forget to take a dose of NURIKA:

If you forget to take a dose of **NURIKA**, take it as soon as you remember, unless it is time for your next dose. In that case, continue to take the next capsule at the usual time. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with NURIKA is stopped:

Do not stop taking **NURIKA** unless your doctor tells you to. If your treatment with **NURIKA** is stopped, it should be done gradually over a minimum of 1 week.

After stopping **NURIKA** treatment, you may experience symptoms such as difficulty in sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, nervousness, depression, pain, increased sweating, and dizziness.

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

4. POSSIBLE SIDE EFFECTS:

NURIKA can have side effects.

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

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

- red, itchy skin rash, blisters or skin peeling
- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to **NURIKA**. 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:

- irregular heart beat or shortness of breath, excessive tiredness and swelling of the legs (indicative of heart failure)
- decreased urination
- seizures (fits)
- yellowing of the eyes or skin.

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

The following side effects may occur frequently:

- increased appetite
- confusion, decreased sexual drive, irritability, disorientation
- dizziness, drowsiness, impaired muscle co-ordination, decreased attention, impaired memory, tremor, difficulty speaking, pins and needles, lack of energy
- blurred or double vision
- dry mouth, constipation, vomiting, flatulence, nausea (feeling ill), loose stools, bloating
- erectile dysfunction
- fatigue, feeling drunk, swelling of the body, abnormal style of walking, falls, feeling abnormal
- increased weight

- difficulty sleeping
- headache, memory loss, numbness, balance disorder
- muscle cramps, joint pain, back pain, pain in limbs, neck spasm.

The following side effects may occur less frequently:

- loss of appetite/weight loss, decreased blood glucose levels
- inability to reach sexual climax, restlessness, feeling depressed, agitation, mood swings, difficulty finding words, hallucinations, abnormal dreams, increased sexual drive, panic attack, elevated mood, aggression, parkinsonism that is symptoms resembling Parkinson's disease such as tremor, bradykinesia (decreased ability to move) and rigidity (muscle stiffness)
- decreased concentration, involuntary eye movement, speech disorder, muscle twitching, reduced reflexes, hyperactivity, sensitive skin, loss of taste, burning sensation, decreased or loss of consciousness, fainting, reduced muscle movement, loss of smell, difficulty writing, mental impairment, feeling unwell
- dry eye, eye swelling, eye pain, watery eyes, light sensitivity, eye irritation, visual disturbances
- increased hearing sensitivity
- hot flushes, high or low blood pressure, coldness in the hands and feet
- short breath, nasal dryness, cough, nasal congestion, nose bleeds, runny nose, snoring, throat tightness
- increased saliva, heartburn, numbness around the mouth, difficulty swallowing, swollen tongue, fluid accumulation in the abdomen, inflamed pancreas (which can cause severe upper abdominal pain, nausea and vomiting)
- joint swelling, muscle pain, muscle stiffness, neck pain
- difficulty urinating
- delayed ejaculation, sexual dysfunction, abnormal or no menstruation, breast pain, breast discharge, enlarged breasts
- weakness, thirst, chest tightness, swelling of the skin, fever, chills
- decreased weight.

The following side effects may also occur:

- reversible loss of ability to move your body
- trouble breathing, shallow breaths.

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 NURIKA.

5. HOW TO STORE NURIKA:

Store at or below 25 °C in the original container.

Keep blisters in the outer carton until required for use. Keep bottles well closed.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

Do not use after the expiry date stated on the box, label or blister.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What NURIKA contains:

The active substance is pregabalin.

NURIKA 25: Each hard capsule contains 25 mg pregabalin

NURIKA 50: Each hard capsule contains 50 mg pregabalin

NURIKA 75: Each hard capsule contains 75 mg pregabalin

NURIKA 150: Each hard capsule contains 150 mg pregabalin

The other ingredients are: maize starch, mannitol, talc.

The capsule shell contains: colourants (titanium dioxide, yellow iron oxide and red iron oxide) and gelatin.

Contains sugar (mannitol).

What NURIKA looks like and contents of the pack:

NURIKA hard gelatin capsules contain a white to off-white, granulated powder.

NURIKA 25: Ivory opaque hard gelatin capsule imprinted in black with '25' on the capsule body.

NURIKA 50: Ivory opaque hard gelatin capsule with the capsule cap imprinted with a radial black band and the capsule body imprinted in black with '50' and a radial black band.

NURIKA 75: Opaque hard gelatin capsule with a pink cap and ivory body imprinted in black with '75'.

NURIKA 150: Ivory opaque hard gelatin capsule imprinted in black with '150' on the capsule body.

Packaging material and pack size:

- **NURIKA 25, 50, 75 & 150** are packed in PVC/aluminium blisters. The blister consists of a silver/grey aluminum foil with a transparent, colourless PVC foil. Blisters are contained in an outer carton.

  Pack size 14: Each carton contains 1 blister strip with 14 capsules per blister.

  Pack size 56: Each carton contains 4 blister strips with 14 capsules per blister.

  Pack size 60: Each carton contains 6 blister strips with 10 capsules per blister.

  Pack size 100: Each carton contains 10 blister strips with 10 capsules per blister.
- **NURIKA 75** is packed in a white, high density polyethylene (HDPE) 150 ml bottle, with a white polypropylene closure with an inner seal. Pack size: 200 capsules.
- **NURIKA 150** is packed in a white, high density polyethylene (HDPE) 300 ml bottle, with a white polypropylene closure with an inner seal. Pack size: 200 capsules.

Not all pack sizes are marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

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