SCHEDULING STATUS

S5

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

INNRIKA 25 Capsules

INNRIKA 75 Capsules

INNRIKA 150 Capsules

Read all this leaflet carefully before you start taking INNRIKA

- 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.
- **INNRIKA** 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 **INNRIKA** is and what it is used for

2. What you need to know before you take **INNRIKA**

3. How to take **INNRIKA**

4. Possible side effects

5 How to store **INNRIKA**

6. Contents of the pack and other information

1. **What INNRIKA is and what is it used for:**

   The active substance of **INNRIKA** is pregabalin. **INNRIKA** 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 INNRIKA:**

   Do not take INNRIKA:

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

   Warnings and precautions

   Take special care with **INNRIKA** if you**:**

- experience the following symptoms swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Some patients taking **INNRIKA** have reported symptoms suggesting an allergic reaction. Should you experience any of these reactions, you should contact your doctor immediately.
- feel dizzy and sleepy, especially if you are over 65 years. There is an increased risk of an accidental fall. You should be careful until you are used to any effect the medicine might have.
- experience a temporary loss in eyesight, blurred vision or any other changes to your sight. You should immediately tell your doctor if you experience any changes in your vision.
- have diabetes and gain weight. You may need an alteration to your diabetic medicines.
- are taking other medicines to treat pain or spasms that have similar side effects to **INNRIKA.** The severity of these effects (e.g. sleepiness) may be increased when taken together.
- are elderly (over 65 years) with a heart condition.
- are suffering from or have suffered from any kidney condition and are finding it difficult to urinate. Your doctor may prescribe a lower dose of INNRIKA.
- are taking other medicines (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.

- have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed and consult your doctor.
- experience a reduction in brain function (encephalopathy). 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, **INNRIKA** should not be used in this age group

Other medicines and INNRIKA:

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

INNRIKA and certain other medicines may influence each other (interaction). When taken with certain other medicines which have sedative effects (including opioids), **INNRIKA** may potentiate these effects, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if **INNRIKA** is taken together with medicines containing:

• Oxycodone (used as a painkiller)

• Lorazepam (used for treating anxiety)

- Alcohol

INNRIKA may be taken with oral contraceptives

INNRIKA with food, drink, and alcohol:

INNRIKA capsules may be taken with or without food. It is advised not to drink alcohol while taking **INNRIKA**

Pregnancy and breastfeeding and fertility:

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 **INNRIKA**.

INNRIKA should not be taken during pregnancy or when breast-feeding. Effective contraception must be used by women of child-bearing potential.

Driving and using machines:

INNRIKA may cause 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

3. How to take INNRIKA:

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

Always take **INNRIKA** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

150mg a day and can be increased by your doctor based on your response and tolerability to 300mg a day after an interval of 3 to 7 days.

INNRIKA must be taken twice a day, once in the morning and once in the evening, at about the same time each day. **INNRIKA** 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 **INNRIKA** until your doctor tells you to stop.

Elderly:

If you are an elderly patient (over 65 years of age), you should take **INNRIKA** 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.

Patients with kidney problems:

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

If you take more INNRIKA than you should:

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

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

In the event of suspected overdose, seek supportive medical care

If you forget to take a dose of INNRIKA:

It is important to take your **INNRIKA** capsules regularly at the same time each day

Do not take a double dose to make up for the forgotten individual doses.

If you forget to take a dose, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose.

If you stop taking INNRIKA

Suddenly stopping your treatment with **INNRIKA** may lead to your symptoms getting worse. Do not stop taking **INNRIKA** 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 **INNRIKA** 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 **INNRIKA** for a longer period. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

INNRIKA can have side effects.

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

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

- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching)
- Skin inflammation, peeling and blistering

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

Tell your doctor if you notice any of the following:

Frequent side effects:

• Dizziness, drowsiness, headache.

- 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.

Less frequent side effects:

- 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 heartbeat, heart failure.
- Flushing, hot flushes.
- Difficulty breathing, dry nose, nasal congestion.
- Increased saliva production, heartburn, numb around mouth.
- 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)
- Liver failure.
- Hepatitis (inflammation of the liver)

Certain side effects may occur more frequently, 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 **INNRIKA** and the severity of these effects may be increased when taken together.

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 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 **INNRIKA.**

5. How to store INNRIKA

- Keep out of reach and sight of children.
- Store at or below 30 °C in the original carton until removed for use.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What INNRIKA contains:

INNRIKA 25, 75, and 150 mg

Black iron oxide, gelatin, potassium hydroxide, pregelatinized starch, propylene glycol, shellac, talc, titanium dioxide.

What INNRIKA looks like and contents of the pack

INNRIKA 25: Opaque white/ Opaque white size “4” Hard gelatin capsules radially imprinted with ‘A’ on cap and ‘140’ on body with black ink filled with white to off white powder.

INNRIKA 75: Opaque white/ Orange Opaque size “4” Hard gelatin capsules radially imprinted with ‘A’ on cap and ‘142’ on body with black ink filled with white to off white powder.

INNRIKA 150: Opaque white/ Opaque white size “2” Hard gelatin capsules radially imprinted with ‘A’ on cap and ‘144’ on body with black ink filled with white to off white powder.

INNRIKA 25, 75 and 150 mg is available in:

Blisters of PVC (forming foil) & Aluminium lidding foil containing 14, 56, 60 & 100 capsules. Such blisters are packed into a carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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South Africa

This leaflet was revised in

New

Registration number

INNRIKA 25: 49/2.5/0304

INNRIKA 75: 49/2.5/0305

INNRIKA 150: 49/2.5/0306

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INNRIKA**