PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NEURONTIN® 100 capsules

NEURONTIN® 300 capsules

NEURONTIN® 400 capsules

NEURONTIN® 600 tablets

NEURONTIN® 800 tablets

Gabapentin

NEURONTIN capsules contain sugar (lactose monohydrate).

Each NEURONTIN 100 capsule contains 14,25 mg lactose monohydrate.

Each NEURONTIN 300 capsule contains 42,75 mg lactose monohydrate.

Each NEURONTIN 400 capsule contains 57,00 mg lactose monohydrate.

NEURONTIN tablets are sugar free.

Read all of this leaflet carefully before you start taking NEURONTIN

- 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.
- NEURONTIN 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 NEURONTIN is and what it is used for

2. What you need to know before you take NEURONTIN

3. How to take NEURONTIN

4. Possible side effects

5. How to store NEURONTIN

6. Contents of the pack and other information

1. What NEURONTIN is and what it is used for

NEURONTIN is used to treat various forms of epilepsy. Your doctor will prescribe NEURONTIN for you to help treat your epilepsy when your current treatment is not fully controlling your condition or where your current treatment is causing problems such as side effects. You should only take NEURONTIN in addition to your current treatment unless told otherwise.

2. What you need to know before you take NEURONTIN

Do not take NEURONTIN

- If you are hypersensitive (allergic) to gabapentin or any of the other ingredients of NEURONTIN (listed in section 6).
- If the patient is less than 12 years of age.
- If you are pregnant, trying to become pregnant or breastfeeding.
- If you suffer from severe kidney problems.

Warnings and precautions

Take special care with NEURONTIN:

- Tell your doctor if you have experienced absence seizures as NEURONTIN may not be an effective treatment.
- Do not allow more than 12 hours between NEURONTIN doses to prevent breakthrough convulsions.
- Treatment with NEURONTIN may cause dizziness and sleepiness, which may increase risk of accidental injury or fall. Confusion, loss of consciousness and mental impairment may also occur.
- If you are taking other medicines, please tell your doctor or pharmacist (see section Other medicines and NEURONTIN). Certain medicines such as opioids, including morphine, may increase the effect of NEURONTIN and cause sleepiness, sedation, breathing problems or death.
- If you have respiratory disorders, nervous system disorders, kidney problems or you are more than 65 years old, your doctor may prescribe a different dosing regimen because of risk of breathing problems (respiratory depression).
- If you develop a rash or other signs or symptoms of hypersensitivity such as fever or enlargement

of lymph nodes, you should tell your doctor immediately as this may be an indication of a serious medical event.

- If you experience a severe allergic reaction (anaphylaxis) which includes the following symptoms: difficulty breathing, swelling of the lips, throat and tongue, and low blood pressure, you should stop using NEURONTIN and ask for immediate medical care.
- A small number of people being treated with NEURONTIN have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your health care provider.
- Cases of abuse and dependence have been reported for NEURONTIN from the post-marketing experience. Talk to your health care provider if you have a history of substance abuse or dependence.

Children and adolescents

Safety and effectiveness in children under 12 years of age have not been established.

Other medicines and NEURONTIN:

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

- In particular, tell your doctor or pharmacist if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.
- If you are taking any medicines containing opioids (such as morphine), please tell your doctor or pharmacist as opioids may increase the effect of NEURONTIN. In addition, combination of NEURONTIN with opioids may cause sleepiness, sedation, decrease in breathing or death.
- NEURONTIN is not expected to interact with other anti-epileptic medicines or with oral contraceptives.
- If NEURONTIN and antacids containing aluminium and magnesium are taken at the same time, the absorption of NEURONTIN from the stomach may be reduced. It is recommended that NEURONTIN be taken about two hours before or after antacid administration.

Pregnancy, breastfeeding and fertility

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

You should not take NEURONTIN while you are pregnant.

The safety of taking NEURONTIN during pregnancy is not known.

Breastfeeding

You should not take NEURONTIN while you are breastfeeding.

Fertility

There is no effect on fertility in animal studies.

Driving and using machines

NEURONTIN may cause dizziness, drowsiness and tiredness.

It is not always possible to predict to what extent NEURONTIN 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 NEURONTIN affects them.

NEURONTIN capsules contain 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 NEURONTIN

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

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

Adults and children over 12 years of age

The usual dose is 900 – 1 800 mg each day in 3 divided doses i.e. in the morning, at midday and at night.

Elderly

Elderly patients may need their dosage adjusted by their doctor.

NEURONTIN can be taken with or without food. Always swallow the capsules or tablets with plenty of water.

Take NEURONTIN at about the same time each day as this will help you remember when to take the capsules or tablets.

Do not alter the dose yourself without your doctor’s advice. Do not stop taking the capsules or tablets

unless told to do so by your doctor.

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

If you take more NEURONTIN than you should

These are the possible signs and symptoms of overdosage: dizziness, double vision, slurred speech, drowsiness, loss of consciousness, tiredness and mild diarrhoea.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any capsules or tablets that are left, the container and the label so that the doctor can identify the medicine you are taking.

If you forget to take NEURONTIN

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

If you forget to take a capsule or tablet, just take one capsules or tablet the following day at the usual time. If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

If you stop taking NEURONTIN

Do not stop taking NEURONTIN unless your doctor tells you to. If your treatment is stopped, it should be done gradually over a minimum of 1 week. If you stop taking NEURONTIN suddenly or before your doctor tells you, there is an increased risk of seizures.

Some side effects that may occur when you stop taking NEURONTIN are headache, pain, confusion, sweating and panic attacks or agitation.

4. Possible side effects

NEURONTIN can have side effects.

Not all side effects reported for NEURONTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NEURONTIN, 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 any of the following happens, stop taking NEURONTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:
- **If you develop a rash or other signs or symptoms of hypersensitivity such as fever or enlargement of lymph nodes, you should tell your doctor immediately as this may be an indication of a serious medical event.**

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Viral infection.
- Respiratory infection.
- Low white blood cell count.
- Increased appetite.
- Confusion.
- Depression.
- Mood changes.
- Nervousness.
- Abnormal thinking.
- Abnormal or lack of coordination.
- Dizziness.
- Drowsiness.
- Memory loss.
- Difficulty speaking.
- Difficulty sleeping.

- Headache.
- Unusual eye movement.
- Tremor.
- Lazy eye.
- Double vision.
- Flushing or dilation of blood vessels.
- Trouble breathing.
- Cough.
- Sore throat.
- Runny nose.
- Stomach pain.
- Constipation.
- Dental abnormalities.
- Diarrhoea.
- Indigestion.
- Dry mouth or throat.
- Nausea.
- Vomiting.
- Acne.
- Itching.
- Rash.
- Back pain.
- Muscle pain.
- Twitching.
- Difficulties with erection (impotence).
- Tiredness.
- Fever.
- Swelling of the hands and feet.
- Decrease in white blood cells.

- Weight gain.
- Abrasion of the skin.
- Fracture.

Less frequent side effects

- Shallow breaths (respiratory depression).

Other side effects

- Decreased platelets (blood clotting cells).
- Allergic reaction including hives.
- Anaphylaxis – a serious, potentially life-threatening allergic reaction including difficulty breathing, swelling of the lips, throat and tongue, and hypotension requiring emergency treatment.
- Allergic reaction that may affect your skin or other parts of your body.
- Increase or decrease in blood glucose levels (most often observed in patients with diabetes).
- Low blood sodium levels.
- Hallucinations.
- Agitation.
- Abnormal movements such as writhing, jerking movements and stiffness.
- Loss of consciousness.
- Ringing in the ears.
- Racing heartbeat (palpitation).
- Chest pain.
- Pancreatitis (inflammation of the pancreas).
- Hepatitis (inflammation of the liver).
- Jaundice (yellowing of the skin and eyes).
- Hair loss.
- Swelling under the skin, usually of the face, lips, tongue, and throat (angioedema).
- Allergic skin reaction with patches of red, raised skin that often look like a bullseye (erythema multiforme).
- A serious disorder of the skin and mucous membranes called Stevens-Johnson syndrome. It starts with flu-like symptoms and is followed by painful rash of small purplish spots that spreads, and then

blisters.

- Symptoms of a serious hypersensitivity reaction called DRESS, including skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of the internal organs.
- Rhabdomyolysis (general weakness, muscle ache/stiffness, decreased urine production).
- Acute kidney failure.
- Loss of bladder control.
- Increased breast tissue.
- Breast enlargement in men.
- Problems with sexual functioning including changes in libido, ejaculation disorders and inability to achieve a sexual climax.
- Adverse events following the abrupt discontinuation of NEURONTIN have been reported e.g. anxiety, difficulty sleeping, nausea, sweating, depression, headache, pain, tremor, agitation, diarrhoea, dizziness, tachycardia (fast heart rate), confusion and generalised oedema (excess fluid in the body) and sudden unexplained deaths.
- Abnormal blood test results suggesting problems with the liver.
- Change in blood test results (increased creatine phosphokinase).
- Fall.

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 **"6.04 Adverse Drug Reactions 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 NEURONTIN.

5. How to store NEURONTIN

Store all medicines out of reach of children.

- Store in a cool, dry place (at or below 25 °C).
- Store in the original package.
- Keep the blister strip 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. The expiry date refers to the last day of that month.
- 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 NEURONTIN contains

The active substance is gabapentin.

Each capsule contains either 100 mg, 300 mg or 400 mg gabapentin.

Each tablet contains either 600 mg or 800 mg gabapentin.

The other ingredients of the capsules are lactose monohydrate, maize starch and talc. The capsule shells consist of gelatine, red iron oxide (400 mg), sodium lauryl sulphate, titanium dioxide, water and yellow iron oxide (300 mg, 400 mg). The printing ink contains indigocarmine Al salt, shellac and titanium dioxide.

The other ingredients of the tablets are copolyvidone K, magnesium stearate, maize starch and poloxamer 407. The film-coating consists of hydroxypropylcellulose and talc. The polishing agent is candelilla wax.

What NEURONTIN looks like and content of the pack

Hard capsules

NEURONTIN 100: White, opaque, hard gelatine capsules imprinted in blue ink with “Neurontin 100 mg” on the cap and “VLE” on the body.

NEURONTIN 300: Light yellow, opaque, hard gelatine capsules imprinted in grey ink with “Neurontin 300 mg” on the cap and “VLE” on the body.

NEURONTIN 400: Grey-orange, opaque, hard gelatine capsules imprinted in grey ink with “Neurontin 400 mg” on the cap and “VLE” on the body.

NEURONTIN 100, 300, 400 capsules: Blister packs of 100 capsules.

Film-coated tablets

NEURONTIN 600: White, elliptical film-coated tablet with bisecting score on both sides, debossed with

“NT” and “16” on one side.

NEURONTIN 800: White, elliptical film-coated tablet with bisecting score on both sides, debossed with “NT” and “26” on one side.

NEURONTIN 600, 800 tablets: Blister packs of 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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Gauteng, 1609

Manufacturer: Viatris Pharmaceuticals LLC, Vega Baja, Puerto Rico

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Registration numbers

NEURONTIN 100 capsules: 27/2.5/0598

NEURONTIN 300 capsules: 27/2.5/0599

NEURONTIN 400 capsules: 27/2.5/0600

NEURONTIN 600 tablets: 35/2.5/0099

NEURONTIN 800 tablets: 35/2.5/0100

BOTSWANA: S2

NEURONTIN 100 – Reg. No.: BOT1101822

NEURONTIN 300 – Reg. No.: BOT1101823

NEURONTIN 400 – Reg. No.: BOT1101824

NAMIBIA: NS3

NEURONTIN 100 – Reg. No.: 04/2.5/1234

NEURONTIN 300 – Reg. No.: 04/2.5/1235

NEURONTIN 400 – Reg. No.: 04/2.5/1236