1.3.2 Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

NEUCAPOR 25 mg

NEUCAPOR 75 mg

NEUCAPOR 150 mg

Pregabalin.

Sugar free.

Read all of this leaflet carefully before you start taking NEUCAPOR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **NEUCAPOR** 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 NEUCAPOR is and what it is used for

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NEUCAPOR belongs to a group of medicines used to treat neuropathic pain due to Herpes zoster infections and diabetes in adults.

2. What you need to know before you take NEUCAPOR

Do not take NEUCAPOR:

If you are allergic to pregabalin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Take special care with NEUCAPOR:

- If you start taking **NEUCAPOR** and experience swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. These are symptoms of an allergic reaction and you should contact your healthcare practitioner immediately.
- If you are taking diabetes medicine and gain weight whilst taking **NEUCAPOR** talk to your doctor as he/she may need to alter the dose of your diabetes medicine.
- **NEUCAPOR** can cause dizziness and somnolence, which can increase the occurrence of accidental injury. You should be extra cautious when taking **NEUCAPOR** until you are used to how you react to it.
- **NEUCAPOR** may cause 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.
- **NEUCAPOR** can cause kidney failure in some patients. If you experience decreased urination whilst taking **NEUCAPOR** you should tell your doctor.

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- Stopping treatment with **NEUCAPOR** after short and long term use may cause withdrawal symptoms such as: difficulty sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, convulsion, excessive sweating and dizziness.
- If you suffer from or have a family history of heart disease you tell your doctor, before commencing treatment with **NEUCAPOR**.
- If you start treatment with **NEUCAPOR** and have thoughts of harming or killing yourself, you should immediately tell your doctor.
- **NEUCAPOR**, when taken with other medicines (certain pain medicines) may cause gastrointestinal problems (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking **NEUCAPOR** you should tell your doctor if you have a history of alcoholism or any drug abuse or dependence. Do not take more medicine than prescribed.
- Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease, because taking **NEUCAPOR** while suffering from such conditions may result in a reduction in brain function (encephalopathy).

Other medicines and NEUCAPOR:

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

NEUCAPOR interacts with the following medicines:

- Oxycodone – (used as a pain-killer)
- Lorazepam – (used for treating anxiety)
- Alcohol

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Taking the above with **NEUCAPOR** may lead to excess dizziness, sleepiness and decreased concentration which could lead to

respiratory failure, coma and death.

NEUCAPOR with food, drink and alcohol

There are no noted interactions between food and **NEUCAPOR**.

NEUCAPOR should not be taken with alcohol.

Pregnancy, breastfeeding and fertility

NEUCAPOR should not be taken during pregnancy or when breastfeeding, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machines

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

3. How to take NEUCAPOR

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

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Always take **NEUCAPOR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **NEUCAPOR** will last. If you have the impression that the effect of **NEUCAPOR** is too strong or too weak, talk to your doctor or pharmacist.

The usual recommended starting dose for **NEUCAPOR** is 75 mg twice daily (150 mg/day), with or without food. This dose may be increased to 150 mg twice daily after an interval of 3 to 7 days

NEUCAPOR is for oral use only.

If you are an elderly patient (over 65 years of age), you should take **NEUCAPOR** normally except if you have problems with your kidneys. You have to discuss this with your doctor.

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

Swallow the capsule whole with water.

Continue taking **NEUCAPOR** until your doctor tells you to stop.

If you take more NEUCAPOR than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

You may feel sleepy, confused, agitated, or restless as a result of taking more **NEUCAPOR** than you should. Fits have also been reported.

If you forget to take NEUCAPOR

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

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4. Possible side effects

NEUCAPOR can have side effects.

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

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

- difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by rash, blisters, peeling skin and pain)

These are all very serious side effects. If you have them, you may have had a serious reaction to **NEUCAPOR**. 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: The following side effects occur frequently:

- jaundice (yellowing of the skin and eyes), nausea, abdominal pain, fatigue and fever
- decreased urinary output, swelling of your legs ankles and feet
- dark, reddish urine, a decreased amount of urine, weakness and muscle aches

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Nausea, vomiting,
- diarrhoea constipation, flatulence,
- feeling bloated,
- dry mouth,

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- increased appetite,
- mood changes, confusion, irritability, disorientation,
- difficulty sleeping,
- decreased libido
- dizziness, excessive sleepiness, headache
- symptoms of ataxia which can be impaired balance and coordination, slurring, coordination abnormal, tremor,
- dysarthria, amnesia, memory impairment, disturbance in attention,
- tingling or prickling sensation (paraesthesia), reduced sense of touch or sensation (hypoesthesia),
- sedation, balance disorder, lethargy,
- blurred vision, double vision,
- vertigo (spinning sensation),
- muscle cramp, muscle pain, back pain, spasm
- erectile dysfunction
- changes in the way you walk, fall, feeling fatigued
- weight gain

Less frequent side effects:

- Low white blood cell count, leaving you prone to infections,
- decreased blood sugar levels,
- anorexia
- seeing, feeling or hearing things that are not there

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- panic attack, restlessness, agitation, depression, depressed mood, elevated mood, aggression, mood swings, depersonalisation, word finding difficulty, abnormal dreams,
- increase libido, inability to orgasm,
- lack of interest or enthusiasm,
- impulsive behaviour, lack of restraint
- temporary loss of consciousness,
- abnormal movement of lips and face, jerky movements of the muscles
- dizziness postural, intention tremor,
- uncontrolled movements of the eye,
- mental impairment, speech disorder,
- absent reflexes,
- loss of taste function of the tongue,
- feeling unwell
- convulsions,
- loss of ability to detect smell,
- decreased body movement,
- Learning disability in the form of poor writing,
- Peripheral vision loss, visual disturbance, eye swelling, visual field defect, eye pain,
- Eye strain, experiencing flashes of light in the field of vision,
- dry eye,
- increase flow of tears, eye irritation
- Vision loss, inflammation of the cornea,
- altered visual depth perception, pupil dilation, visual brightness,

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- hearing sensitivity,
- slow, fast, irregular or abnormal heartbeat, heart problems,
- increase or decrease in blood pressure, hot flushes feeling cold
- shortness of breath, cough, nasal congestion and dryness, snoring,
- collection of fluid in the lungs,
- difficulty swallowing, swelling of the tongue, increased saliva production, heartburn, numb around mouth
- Muscle twitching, joint swelling, muscle stiffness, pain including muscle pain, neck pain.
- delayed ejaculation
- menstrual cramps, irregular menstruation, breast pain, breasts discharge and enlargement
- development of breasts in males
- chest tightness, pain, fever, thirst, chills, abnormal physical weakness or lack of energy
- Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, platelet count decreased, neutropenia, increase in blood creatinine, decrease in blood potassium)
- increased bleeding tendency
- low blood platelet count, resulting in sever bleeding
- nosebleeds
- dry mouth
- indigestion
- inflammation of the liver
- joint pain, aching muscles including muscle cramps
- abnormal physical weakness or lack of energy

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Frequent unknown side effects:

Suicidal ideation and Suicidal behaviour

If you notice any side effects not mentioned in this leaflet,

inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NEUCAPOR

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

Keep HDPE containers tightly 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 (e.g. toilets).

6. Contents of the pack and other information

What NEUCAPOR contains

NEUCAPOR contains the active substance pregabalin.

The other ingredients of **NEUCAPOR** are:

- Maize starch Ph.Eur
- Talc Ph.Eur

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- Empty hard gelatine capsule shell

NEUCAPOR 25 mg:

1. Constituents of the capsule:

The capsule shell contains:

- Gelatine,
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171).

2. Constituents of the printing ink:

- The printing ink contains:
- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NEUCAPOR 75 mg:

1. Constituents of the capsule:

The capsule shell contains:

- Gelatine,
- Sodium lauryl sulphate

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- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171)
- Iron oxide red (E No: 172)

2. Constituents of the printing ink:

The printing ink contains:

- Shellac
- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

NEUCAPOR 150 mg:

1. Constituents of the capsule:

The capsule shell contains:

- Gelatine,
- Sodium lauryl sulphate
- Water
- Titanium dioxide (C.I. No: 77891 and E No: E 171)

2. Constituents of the printing ink:

The printing ink contains:

- Shellac

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- Dehydrated Alcohol
- Isopropyl alcohol
- Butyl Alcohol
- Propylene Glycol
- Strong Ammonia solution
- Black Iron oxide (C.I. No: 77499)
- Potassium hydroxide
- Purified water

What NEUCAPOR looks like and contents of the pack

NEUCAPOR 25 mg:

Capsules, hard. White cap / White body, size '5' hard gelatine capsule shells, imprinted with "Z" on cap and "10" on body with black ink contains white to off-white granular powder.

The dimensions of the size '5' capsules are as follows:

Length:

6.2±0.4 mm for the cap,

9.3±0.4 mm length for the body

Width:

4.91±0.03 mm for the cap

4.65±0.03 mm for the body

NEUCAPOR 75 mg:

Capsules, hard. Orange cap / white body, size '4' hard gelatine capsule shells, imprinted with "Z" on cap and "12" on body with black ink contains white to off-white granular powder.

The dimensions of the size '4' capsules are as follows:

Length:

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7.2±0.4 mm for the cap,

12.2±0.4 mm length for the body

Width:

5.33±0.03 mm for the cap

5.06±0.03 mm for the body

NEUCAPOR 150 mg:

Capsules, hard. White cap / white body, size '2' hard gelatine capsule shells, imprinted with "Z" on cap and "14" on body with black ink contains white to off-white granular powder.

The dimensions of the size '2' capsules are as follows:

Length:

9±0.4 mm for the cap,

15.2±0.4 mm length for the body

Width:

6.37±0.03 mm for the cap

6.08±0.03 mm for the body

NEUCAPOR 25 mg

1) Blister Pack:

Capsules are packed in an aluminium foil blister pack.

Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

2) HDPE Pack:

Capsules are packed in white opaque round 40 mL HDPE bottle.

Pack size: 60's – One HDPE container contains 60 capsules.

NEUCAPOR 75 mg

1) Blister Pack:

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Capsules are packed in an aluminium foil blister pack.

Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

2) HDPE Pack:

Capsules are packed in white opaque round 60 mL HDPE bottle.

Pack size: 60's – One HDPE container contains 60 capsules.

[PRODCUT NAME] 150 mg

1) Blister Pack:

Capsules are packed in an aluminium foil blister pack

Pack size: 60's – Each carton contains 6 blisters of 10 capsules each.

2) HDPE Pack:

Capsules are packed in white opaque round 75 mL HDPE bottle.

Pack size: 60's – One HDPE container contains 60 capsules.

HOLDER OF THE CERTIFICATE OF REGISTRATION

Aurogen SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

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South Africa

Registration number

NEUCAPOR 25 mg 48/2.5/1070
NEUCAPOR 75 mg 48/2.5/1071
NEUCAPOR 150 mg 48/2.5/1072

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