PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

NUBACAP 25, 75 and 150 hard gelatine capsule

Pregabalin

NUBACAP is sugar free

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

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

NUBACAP is used to treat adults with long lasting pain (also called neuropathic pain) caused by damage to the nerves. Diseases like diabetes (high blood glucose levels) and shingles (a painful acute inflammation of the nerves, with a skin eruption often forming a girdle around the middle of the body) can cause neuropathic pain.

2. What you need to know before you take NUBACAP

Do not take NUBACAP:

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

Warnings and Precautions

Take special care with NUBACAP:

- If you experience symptoms such as swelling of the face, lips, tongue and throat, as well as diffuse skin rash, you may have had a serious allergic reaction to NUBACAP. Stop taking NUBACAP immediately.
  These are all very serious side effects and you may need urgent medical attention or hospitalisation (see "**Possible side effects**").
- Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with pregabalin. Stop using NUBACAP and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions as described in section 4.
- If you are a diabetic and are taking medicine to control your blood glucose levels. You might gain weight while taking NUBACAP and may need an alteration in your diabetic medicines.
- If you have a history of heart disease.
- If while taking NUBACAP you notice a decrease in urination (passing less urine than is normal for you), you should tell your doctor.
- If you have a spinal cord injury, as you may be taking other medicines that have similar side effects to NUBACAP and the severity of these effects may be increased when taken together.
- If you take NUBACAP with medicines that are used to treat depression, as you may experience respiratory failure (symptoms include difficulty breathing or shortness of breath, especially when active, coughing up mucous, wheezing and rapid breathing).

- NUBACAP has been associated with dizziness and drowsiness, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect NUBACAP might have (see "**Driving and using machines**").
- You may experience convulsions (fits) when taking NUBACAP or shortly after stopping NUBACAP. If you experience a convulsion (fit), contact your doctor immediately.
- NUBACAP 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.
- If you develop thoughts of harming or killing yourself while taking NUBACAP contact your doctor immediately.
- When NUBACAP 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 any substance abuse or dependence. Do not take more NUBACAP than prescribed.
- Tell your doctor if you have a history of any serious medical conditions, including liver or kidney problems. There have been reports of reduction in brain function (encephalopathy) in some patients taking NUBACAP when they have other conditions.
- There have been reports of breathing difficulties with NUBACAP. 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.

Children and adolescents

- If you are under 18 years of age you should not take NUBACAP.

The safety and effectiveness in children and adolescents (under 18 years of age) have not been established.

Other medicines and NUBACAP:

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

Tell your doctor or pharmacist if you are currently using:

- Oxycodone (used to treat pain).
- Lorazepam (used to treat anxiety).

NUBACAP with food, drink and alcohol:

NUBACAP may be taken with or without food.

Do not take NUBACAP with alcohol.

Pregnancy, breastfeeding and fertility:

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 health care provider for advice before taking this medicine.

Do not take NUBACAP if you are pregnant or breastfeeding.

Driving and using machines:

NUBACAP frequently causes dizziness and drowsiness and can affect your ability to drive a vehicle and use machines. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NUBACAP affects you.

3. How to take NUBACAP

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

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

The usual starting dose of NUBACAP is 75 mg twice daily (150 mg/day), with or without food.

Based on your individual response and tolerability, your dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.

Your doctor will tell you how long your treatment with NUBACAP will last.

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

If you take more NUBACAP than you should:

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

Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken.

If you forget to take a dose of NUBACAP:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take NUBACAP at the next regularly scheduled time.

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

Effects when treatment with NUBACAP is stopped:

Do not stop taking NUBACAP unless your doctor tells you to. If your treatment is stopped, it should be done gradually over a minimum of one (1) week.

After stopping long-term or short-term NUBACAP treatment, you may experience side effects such as trouble sleeping, headache, nausea (feeling sick), feeling anxious, diarrhoea, flu-like symptoms, convulsions (fits), nervousness, depression, pain, sweating and dizziness. These symptoms may occur more commonly or severely if you have been taking NUBACAP for a longer period

of time.

4. Possible side effects

NUBACAP can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, skin, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

- Changes in the way your heart beats, if you notice it beating faster or slower or skipping a beat.
- Heart rhythm disturbances.
- Chest pain or tightness.
- Congestive heart failure (a heart disease with shortness of breath and swelling of the feet or legs due to fluid build-up).
- Difficulty in breathing.
- Pulmonary oedema (a condition caused by excess fluid in the lungs).
- Signs of recurrent infections such as fever, sore and swollen throat, cough, blocked or runny nose.

- Inflammation of the pancreas (symptoms include nausea (feeling sick), vomiting (being sick), fever, swollen and tender stomach, fast heart rate).
- Loss of consciousness, mental impairment, reversible paralysis (loss of the ability to move), convulsions (fits).
- 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 difficulty 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.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Increased appetite, increased weight.
- Feeling extremely happy, confused, irritable or disorientated.
- Dizziness, drowsiness, headache, tiredness.
- Unsteadiness when walking, abnormal coordination, problems with your balance, abnormal way of walking.
- Memory impairment, abnormal thinking, disturbance in attention, loss of memory.
- Difficulty in speaking, tingling or numbness of the hands and feet, shaking (tremors).
- Uncontrollable twitching, jerking movements, spasmodic contraction of groups of muscles.
- Blurred vision or double vision.

- Vertigo (spinning sensation), feeling drunk.
- Over-sensitivity to certain frequency and volume ranges of sound.
- Dry mouth, constipation, nausea (feeling sick), diarrhoea, vomiting (being sick), flatulence (gas/wind).
- Decreased sexual drive, the inability to get or keep an erection.
- Accidental injury due to a fall.
- A sudden feeling of cold with shivering accompanied by a rise in temperature, pain, thirst.

Less frequent side effects:

- Loss of appetite, low sugar levels in the blood (symptoms may include sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat).
- Feeling nervous, depressed, restless, agitated.
- Persistent inability to achieve orgasm despite responding to sexual stimulation, increased sexual drive.
- Mood swings, inability to sleep, seeing, feeling or hearing things that are not there, abnormal dreams.
- Having thoughts and feelings that seem unreal and not to belong to yourself.
- Acute anxiety (symptoms include difficulty breathing, chest pain, fast heart rate), elevated or depressed mood.
- Lack of interest, enthusiasm or concern.
- Difficulty in finding words, difficulty with writing properly.
- Decreased or increased feeling or sensitivity, especially in the skin.
- Slow body movement, abnormal weakness of certain muscles, numbness or weakness of the arms and legs, fainting.
- Loss of taste function, loss of smell.
- Dry, swollen, painful, irritated eyes.
- Dilated pupils, tears flowing from the eyes.

- Presence of perceived flashes of light.
- Altered visual depth perception.
- Abnormal alignment of the eyes (the condition of having a squint).
- Rapid, uncontrolled movements of the eyes.
- High or low blood pressure, flushing, hot flushes, cold hands and feet.
- Bloated stomach, an excessive secretion of saliva.
- Gastro-oesophageal reflux disease, a digestive disorder that affects the ring of muscle between the oesophagus and stomach.
- The accumulation of fluid causing abdominal swelling.
- Difficulty in swallowing.
- Bleeding nose, snoring.
- Excessive sweating, itchy rash, skin rash with flat, red areas.
- Muscle twitching, muscle cramp, muscle stiffness, painful muscles.
- Back pain, pain in the arms or legs, neck pain or spasm.
- Swollen and painful joints.
- Breast enlargement in men and women, breast pain.
- Painful menstruation or no menstruation.
- Weight loss.
- Changes in blood and liver test results.

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 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 NUBACAP.

5. How to store NUBACAP

Store at or below 30 °C.

Keep blister strips in the carton until required for use.

Protect from light and moisture.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NUBACAP contains

The active substance is pregabalin.

Each capsule contains 25 mg, 75 mg or 150 mg pregabalin respectively.

The other ingredients are pregelatinised starch and talc.

The capsule shell contains gelatine and titanium dioxide, and is imprinted with black printing ink (consisting of black iron oxide and shellac).

The capsule shell of NUBACAP 75 also contains iron oxide red (colourant).

What NUBACAP looks like and contents of the pack

NUBACAP 25: 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.

NUBACAP 75: Opaque white and opaque orange, size “4” hard gelatine capsules, radially imprinted with ‘A’ on cap and ‘142’ on body with black ink, filled with white to off-white powder.

NUBACAP 150: 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.

NUBACAP 25, 75 and 150 are packed in blister strips of clear PVC/aluminium

and packed into an outer cartons.

Pack size: 10, 14, 56, 60 or 100 capsules.

Holder of certificate of registration

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