PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEXOMEP 20 (tablets)

NEXOMEP 40 (tablets)

Esomeprazole

Each NEXOMEP 20 tablet contains sugar spheres (sucrose + glucose 16,13 mg).

Each NEXOMEP 40 tablet contains sugar spheres (sucrose + glucose 32,26 mg).

Read all of this leaflet carefully before you start taking NEXOMEP

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

2. What you need to know before you take NEXOMEP

3. How to take NEXOMEP

4. Possible side effects

5. How to store NEXOMEP

6. Contents of the pack and other information

1. What NEXOMEP is and what it is used for

NEXOMEP is used to treat the following conditions:

- ***Gastro-Oesophageal Reflux Disease (heartburn). This is where acid from the stomach escapes into the oesophagus (the tube that connects your throat to your stomach) causing pain, inflammation and heartburn:***
    - Prevention of relapse in patients with healed inflammation of the oesophagus.
- ***As part of the treatment for:***
    - Ulcers in the stomach or upper part of the intestine that are infected with bacteria called "*Helicobacter pylori*".
    - Reduction of risk of recurrence of ulcers in the stomach that are infected with the bacteria *Helicobacter pylori*.

2. What you need to know before you take NEXOMEP

Do not take NEXOMEP:

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of NEXOMEP (listed in section 6), or other medicines in this group.
- If you are taking a medicine called atazanavir or nelfinavir (used to treat HIV).

Warnings and precautions

Take special care with NEXOMEP:

Tell your doctor:

- *If any of the following happen to you before you start taking NEXOMEP or while you are taking it, as NEXOMEP can hide the symptoms of other diseases:*
    - You lose a lot of weight for no reason and have problems swallowing.
    - You get stomach pain or indigestion.
    - You begin to vomit food or blood.
    - You pass black stools (blood-stained faeces).
- If you have been taking NEXOMEP for over a year as you need to be monitored regularly.
- If you suffer from liver disease.

- If you have been prescribed NEXOMEP on an “as needed” basis, you should contact your doctor if your symptoms continue or change in character.
- If you get severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.
- NEXOMEP may reduce the absorption of vitamin B12, especially on long-term therapy. Talk to your doctor or pharmacist if you are taking vitamin B12.
- If you are on NEXOMEP for more than 3 months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Taking a proton pump inhibitor like NEXOMEP, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you are due to have a specific blood test (Chromogranin A).
- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with NEXOMEP. Remember to also mention any other ill-effects like pain in your joints.

NEXOMEP is not recommended for mild ailments of the stomach and intestines such as indigestion.

Children and adolescents

NEXOMEP is not recommended for use in children below the age of 12 years, as its safety and efficacy has not been demonstrated in this age group.

Other medicines and NEXOMEP

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

NEXOMEP can reduce the effectiveness of:

- Ketoconazole and itraconazole (medicines used to treat fungal infections),
- Imipramine (used to treat depression),
- Several antipsychotic medicines (medicines used to treat certain psychiatric disorders),
- Tacrine (used to treat Alzheimer's disease),
- Theophylline (used in treatment of certain respiratory diseases),
- Atazanavir and nelfinavir (used to treat HIV),
- Erlotinib (used for certain types of cancer),
- Clopidogrel (used to prevent blood clots).

Do not take NEXOMEP if you are taking these medicines.

NEXOMEP may increase the blood concentrations of the following medicines:

- Diazepam (used to treat anxiety and epilepsy or relax muscles),
- Citalopram (used to treat depression),
- Imipramine or clomipramine (used to treat behaviour disorders, depression or panic)
- Warfarin (used to thin blood),
- Phenytoin (used in epilepsy),
- Saquinavir (a medicine used to treat HIV),
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer),
- Tacrolimus (organ transplantation),
- Digoxin (used for heart problems),
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply),
- Cisapride (used for indigestion and heartburn).

Your doctor may decide to reduce your dose of these medicines.

With voriconazole (used to treat fungal infections), the effectiveness of both medicines may be increased. Your doctor may therefore decide to reduce your dose of NEXOMEP.

Clarithromycin (an antibiotic used to treat infections) may increase the blood levels of NEXOMEP.

Rifampicin (used for treatment of tuberculosis) and St. John's wort *(Hypericum perforatum)* (used to treat depression) may reduce the effectiveness of NEXOMEP.

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 healthcare provider for advice before taking NEXOMEP.

The safety of NEXOMEP in pregnant and breastfeeding women has not yet been established. You should not take NEXOMEP if you are pregnant or breast-feeding your baby.

Driving and using machines

NEXOMEP may cause dizziness and may affect the ability to drive or use machines.

NEXOMEP contains sucrose and glucose

NEXOMEP tablets contain sucrose and glucose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NEXOMEP.

3. How to take NEXOMEP

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

Always take NEXOMEP exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of NEXOMEP is too strong or too weak, talk to your doctor or pharmacist.

If symptom control has not been achieved after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

Method of administration:

NEXOMEP should be swallowed whole with liquid and not chewed or crushed.

NEXOMEP is used to treat the following conditions:

- *Gastro-Oesophageal Reflux Disease (heartburn):*
  - The usual dose is 40 mg once daily for 4 weeks.
  - Prevention of relapse in patients with healed inflammation of the oesophagus: 20 mg once daily.
  - Treatment of symptoms associated with gastro-oesophageal reflux disease (heartburn): 20 mg once daily.
- *Duodenal ulcer associated with Helicobacter pylori:*
  - 20 mg twice daily for 7 days.

Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

Impaired liver function:

If you have severe liver function impairment, your doctor may prescribe a dose of 20 mg NEXOMEP once daily.

If you take more NEXOMEP than you should

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

If you forget to take NEXOMEP

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking NEXOMEP and contact a doctor immediately:

- Sudden wheezing, swelling of the lips, tongue and throat or body, rash, fainting or difficulties in swallowing. These can be signs of a severe allergic reaction,
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis',
- Yellow skin and whites of the eyes, dark urine and tiredness which can be symptoms of liver problems.

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

Consult your doctor as soon as possible if any of the following side effects continue or are bothersome:

The following side effects have been reported frequently:

- Headache,
- Diarrhoea, stomach pain, constipation, flatulence (wind),

- Nausea, vomiting,
- Benign polyps (non-cancerous growths) in the stomach.

The following side effects have been reported less frequently:

- A reduction in the number of white blood cells, which may lead to more frequent infections,
- A reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal,
- Coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests),
- Swelling of the extremities (peripheral oedema),
- Decreased sodium level in blood,
- Sleep disorders,
- Agitation,
- Confusion,
- Depression,
- Aggression,
- Hallucinations,
- Disturbances in vision such as blurred vision,
- Spinning feeling (vertigo),
- Skin rash, lumpy rash (hives), itchy skin,
- Hair loss,
- Skin sensitivity on exposure to sunshine,
- Joint pains, muscle pains, muscle weakness,
- Kidney problems such as painful urination and lower back pain with fever,
- Dizziness,
- Feeling of tingling, prickling, pins and needles, burning sensation or numbness,
- Feeling drowsy or sleepy,

- Distortion or complete lack of the sense of taste,
- Dry mouth,
- An inflammation of the inside of the mouth,
- An infection called “thrush” which can affect the gut and is caused by a fungus,
- An increase in liver enzymes,
- Severe liver problems leading to liver failure and inflammation of the brain,
- Nose infection, chest infection,
- Difficulty breathing,
- Breast enlargement in males,
- Feeling weak, exhausted or generally unwell,
- Increased sweating.

The frequency of the following side effects are unknown:

- Decreased magnesium level in blood (see section 2),
- Inflammation in the gut, leading to diarrhoea (macroscopic colitis),
- Skin rash on areas exposed to sunlight (subacute cutaneous lupus erythematosus).

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 NEXOMEP.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store NEXOMEP

- Store at or below 25 °C.
- Do not remove the blister from the carton until required for use.

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container.
- 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 NEXOMEP contains

Active ingredient:

Each Nexomep 20 gastro-resistant tablet contains esomeprazole magnesium dihydrate which is equivalent to 20 mg esomeprazole.

Each Nexomep 40 gastro-resistant tablet contains esomeprazole magnesium dihydrate which is equivalent to 40 mg esomeprazole.

The other ingredients are:

Tablet core:

Sugar spheres (composed of sucrose, maize starch and liquid glucose)

Hydroxypropylcellulose

Povidone

Talc

Titanium dioxide (E171)

Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 %

Glycerol monostearate 40 to 55 *Type II*

Propylene glycol

Stearic acid *Type 50*

Polysorbate 80

Simeticone

Microcrystalline cellulose

Macrogol 6000

Crospovidone *Type A*

Silica colloidal anhydrous

Magnesium stearate

Tablet coating:

Hypromellose

Macrogol 6000

Titanium dioxide (E171)

Talc

Ferric oxide red (E172)

Ferric oxide yellow (E172) (only present in NEXOMEP 20).

What NEXOMEP looks like and contents of the pack

Nexomep 20 mg: Light pink oval film-coated tablet.

Nexomep 40 mg: Pink oval film-coated tablet with a score line on both sides.

(i) Aluminium (soft)/Aluminium (hard) blister cards.

(ii) Bottles (polyethylene bottles) closed with polypropylene caps with desiccant inserts.

Packed in 14 or 28 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Marketed by Unicorn Pharmaceuticals (Pty) Ltd

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07