PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEXIPRAZ 20 Gastro-resistant tablet

The active substance is esomeprazole magnesium 20,7 mg equivalent to esomeprazole 20 mg.

Contains 30 mg sucrose per tablet:

NEXIPRAZ 40 Gastro-resistant tablet

The active substance is esomeprazole magnesium 41,4 mg equivalent to esomeprazole 40 mg.

Contains 60 mg sugar per tablet

Read all of this leaflet carefully before you start taking NEXIPRAZ tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **NEXIPRAZ** 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 NEXIPRAZ IS AND WHAT IT IS USED FOR

NEXIPRAZ contains esomeprazole which belongs to a group of medicines known as proton pump inhibitors.

NEXIPRAZ tablets are used:

- in the treatment of gastroesophageal reflux disease (a condition in which gastric content may rise up to the oesophagus and which can be associated with oesophagitis) caused by acid secretion and the associated symptoms such as heartburn, acidic belches and pain on swallowing.
- in the long-term treatment and in the prevention of reflux oesophagitis (a condition in which backwash of gastric content in oesophagus leads to inflammation and pain).
- in combination with appropriate medicines (antibacterials) for healing *Helicobacter pylori* (*Helicobacter pylori*- a microorganism which may cause gastric or duodenal ulcers) associated duodenal ulcer and prevention of peptic ulcers reappearing in patients with *Helicobacter pylori* associated ulcers
- in the healing and prevention of gastric and duodenal ulcers caused by anti-inflammatory medicines in some patients needing continuous treatment with anti-inflammatory medicines (e.g. aspirin and ibuprofen)

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXIPRAZ

Do not take NEXIPRAZ:

- if you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of **NEXIPRAZ** tablets (see section "**WHAT NEXIPRAZ CONTAINS**" for further information).
- if you are allergic to any other proton pump inhibitors (medicines that decrease the secretion of acid from the stomach).
- if you are taking atazanavir or nelfinavir for HIV.

Warnings and precautions

Special care should be taken with **NEXIPRAZ**

- if you suffer or have recently suffered from any of the following symptoms: unintentional weight loss, recurrent vomiting or vomiting of blood, or dark stool or difficulty in swallowing. Your doctor may perform additional investigations in order to diagnose your condition and/or exclude malignant disease.
- **NEXIPRAZ** is not indicated for mild gastric complaints like mild pain in the abdomen, abdominal fullness and feeling full earlier than expected when eating due to nervousness, tension, or anxiety.
- if you take **NEXIPRAZ** tablets on a long-term basis (longer than 1 year), your doctor may keep you under regular monitoring.
- If you are taking clopidogrel for blood clotting.

Diarrhoea: **NEXIPRAZ** may increase your risk of getting severe diarrhoea. This diarrhoea may be caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.

Bone fractures: People who take Proton Pump Inhibitor medicines, such as in **NEXIPRAZ,** for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist, or spine. You should take **NEXIPRAZ** exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed. Talk to your doctor about your risk of bone fracture if you take **NEXIPRAZ**.

Low magnesium levels in your body: Low magnesium can happen in some people who take a proton pump inhibitor medicine (such as **NEXIPRAZ**) for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium. Tell your doctor right away if you have any of the following symptoms: seizures, dizziness, tiredness, abnormal or fast heartbeat, muscle cramps or spasm.

Vitamin B deficiency: **NEXIPRAZ** reduces the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B12 properly. Talk to your doctor about the possibility of vitamin B12 deficiency if you have been taking **NEXIPRAZ** for a long time (more than 3 years).

Subacute chronic lesions on the skin and mucous membranes: Proton pump inhibitor medicines, such as **NEXIPRAZ,** are associated with very infrequent cases of this condition. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in joints, the patient should seek medical

help immediately and the health care professional should consider stopping **NEXIPRAZ**. The condition after previous treatment with a proton pump inhibitor may increase the risk of the condition with other proton pump inhibitors.

Effect on the kidneys: Proton pump inhibitor medicines, such as **NEXIPRAZ,** may rarely cause interstitial nephritis which can lead to inflammation that affects the tubules of the kidneys and the tissues that surround them. This condition may progress to kidney failure and is not necessarily reversed when treatment is discontinued.

Other medicines and NEXIPRAZ:

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

- atazanavir or nelfinar, used to treat HIV infection.
- ketoconazole, itraconazole or voriconazole, used to treat fungal infections since **NEXIPRAZ** may affect its concentration in your body.
- to thin your blood, such as warfarin. It may be necessary to monitor your blood coagulation more often.
- to prevent blood clots, such as clopidogrel. **NEXIPRAZ** and clopidogrel should not be used together as the effect of clopidogrel may be reduced.
- benzodiazepines, such as diazepam (used in the treatment of anxiety) and phenytoin (used to treat seizures).
- citalopram, imipramine or clomipramine, used to treat depression.
- methotrexate, a chemotherapy medicine used in high doses to treat cancer.
- tacrolimus, used for organ transplantation.
- erlotinib, used to treat cancer.
- digoxin, used for heart problems.
- cilostazol, used to treat pain in your legs when you walk which is caused by an insufficient blood supply.
- rifampicin, used to treat tuberculosis.

- St John's wort, used to treat depression.
- cisapride, used for indigestion and heartburn.
- If your doctor has prescribed amoxicillin and clarithromycin to get rid of your *Helicobacter pylori* in order to heal your ulcer, it is essential that you tell your doctor about any other medicines you are taking.
- **NEXIPRAZ** contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Pregnancy and breastfeeding

Do not take **NEXIPRAZ** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **NEXIPRAZ**.

Driving and using machines

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

3. HOW TO TAKE NEXIPRAZ

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

You should swallow the tablet(s) whole, with water. Do not crush, break or chew the tablet(s).

If you have difficulty in swallowing, the tablets can also be dispersed in half a glass of non-carbonated water. No other liquids should be used as the enteric coating may be dissolved. Stir until the tablets disintegrate and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with half a glass of water and drink. The pellets must not be chewed or crushed.

The usual dose of **NEXIPRAZ** is mentioned below:

Symptoms of gastroesophageal reflux disease

The usual dose for the treatment of the symptoms of gastroesophageal reflux disease is one tablet of **NEXIPRAZ** 20 mg per day. Your doctor will tell you how long to continue taking the medicine.

Treatment of gastroesophageal reflux disease

The usual dose for the treatment of acid reflux is 40 mg (2 x 20 mg tablets or 1 x 40 mg tablet) per day for 4 weeks. Your doctor will tell you how long to continue taking the medicine.

Long-term treatment to prevent reappearance of reflux oesophagitis

For long term treatment the recommended dose is 1 tablet of **NEXIPRAZ** 20 mg once daily

In combination with appropriate medicines (antibacterials) for healing *Helicobacter pylori*

NEXIPRAZ 20 mg tablet two times a day for 7 days.

Prevention and healing of gastric and duodenal ulcers caused by anti-inflammatory medicines (NSAIDs) in patients at risk

The recommended dose is 1 to 2 tablets of **NEXIPRAZ** 20 mg (or 1 tablet of **NEXIPRAZ** 40 mg) daily.

If you have the impression that the effect of **NEXIPRAZ** is too strong or too weak, talk to your doctor or pharmacist.

Children

NEXIPRAZ should not be used in children younger than 12 years.

If you take more NEXIPRAZ than you should

If you take more NEXIPRAZ 20 mg or 40 mg tablets than you should call your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take along any tablets that are left, the container and the label so that the hospital can easily tell what medicine you have taken.

If you forget to take NEXIPRAZ

If you forget to take a dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet. If you miss several doses, contact your doctor.

Effects when treatment with NEXIPRAZ is stopped

Do not stop taking **NEXIPRAZ** unless on your doctor's advice.

If you have any further questions on the use of **NEXIPRAZ**, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

NEXIPRAZ can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, tongue 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 allergic reaction to **NEXIPRAZ**. 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:

Less frequent:

- Yellowing of the skin and whites of the eyes, also called jaundice.
- Skin reactions (including skin rashes, hives, inflammation or swelling, blistering, peeling, loosening of skin, red skin lesions, often with a purple centre, sores or ulcers).
- Blood disorders associated with sore throat, fever or chills; cough or hoarseness; lower back or side pain; painful or difficult urination; unusual bleeding or bruising; black, tarry stools; blood in urine or stools; pinpoint red spots on skin.

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

Tell your doctor if you notice any of the following:

Frequent:

Headache, abdominal pain, diarrhoea, gas, nausea/vomiting, constipation, skin rashes.

Less frequent:

Dizziness, sleepiness, unusual tiredness or weakness, trouble in sleeping, confusion, agitation, hallucinations (seeing, hearing, or feelings things that are not there), depression, aggression, bronchospasm (suddenly feeling wheezy or short of breath), dry mouth, taste disturbances, sores in the mouth, blurred vision, hair loss, increased sweating, impotence, enlarged breasts in men, vertigo (sense of constant movement of self or surroundings), joint or muscle pain, fracture of the hip, wrist or spine (see **Take special care with NEXIPRAZ**), changes in blood tests that check how the liver is working, blood problems such as a reduced number of white blood cells or platelets, low levels of sodium in the blood, an infection called “thrush” which can affect the gut, severe kidney problems.

Frequency unknown:

Low magnesium levels in your body (see **Take special care with NEXIPRAZ**), severe liver problems leading to liver failure and inflammation of the brain.

You may also get severe diarrhoea characterised by watery stools, stomach pain, fever (*Clostridium difficile* associated diarrhoea).

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. 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 providing information on the safety of **NEXIPRAZ.**

5. HOW TO STORE NEXIPRAZ

Store at or below 25 °C, protected from moisture. Do not remove the blisters from the carton until required for use.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not store in bathrooms in order to protect from moisture.

Do not use after the expiry date stated on the label.

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 NEXIPRAZ contains

The active substance is esomeprazole magnesium 20,7 mg and 41,4 mg equivalent to esomeprazole 20 mg and 40 mg respectively.

The other ingredients are sucrose, crospovidone, diethlyphthalate, hydroxypropyl cellulose, hypromellose phthalate, polyethylene glycol, purified talc, microcrystalline cellulose, povidone and sodium stearyl fumarate. Film coating material: Opadry brown, polyethylene glycol.

What NEXIPRAZ looks like and contents of the pack

NEXIPRAZ 20

Light brick red to brown coloured, oval, biconvex, film coated tablets with '**E5'** debossed on one side and plain on the other side.

NEXIPRAZ 40

Light brick red to brown coloured, oval, biconvex, film coated tablets with 'E6' debossed on one side and plain on the other side.

Blister pack

The carton contains 14, 28 or 30 tablets packed in cold form blister strips or desiccant embedded cold form blister strips. Each blister strip contains 7 or 10 tablets.

Plastic HDPE bottle

The carton contains white opaque HDPE bottle with screw cap closure containing 30 tablets.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

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