

## Patient Information Leaflet

### SCHEDULING STATUS:

S2

### **NEXIPRAZ OTC** Gastro-resistant tablets

Esomeprazole magnesium 20,7 mg equivalent to esomeprazole 20 mg.

Contains 30 mg sugar (sucrose) per tablet.

### **Read all of this leaflet carefully before you start taking NEXIPRAZ OTC**

- Keep this leaflet. You may need to read it again.
- Do not share **NEXIPRAZ OTC** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

### **What is in this leaflet**

1. What **NEXIPRAZ OTC** is and what it is used for
2. What you need to know before you take **NEXIPRAZ OTC**
3. How to take **NEXIPRAZ OTC**
4. Possible side effects
5. How to store **NEXIPRAZ OTC**
6. Contents of the pack and other information

### **1. WHAT NEXIPRAZ OTC IS AND WHAT IT IS USED FOR**

**NEXIPRAZ OTC** contains the active substance esomeprazole. It belongs to a group of medicines called 'proton pump inhibitors.' They work by reducing the amount of acid that your stomach produces.

**NEXIPRAZ OTC** is indicated for the temporary short-term relief of heartburn and hyperacidity. Heartburn is the painful sensation in the chest rising up to your throat.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXIPRAZ OTC**

Do not take **NEXIPRAZ OTC**:

- if you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of **NEXIPRAZ OTC** tablets (see section “**WHAT NEXIPRAZ OTC CONTAINS**” for further information).
- if you are taking atazanavir or nelfinavir for HIV.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

### **Warnings and precautions**

Special care should be taken with **NEXIPRAZ OTC** if:

- You have had a stomach ulcer or stomach surgery in the past.
- You have been taking treatment continuously for reflux or heartburn for 4 or more weeks.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems. Proton pump inhibitor medicines, such as **NEXIPRAZ OTC**, 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.
- You need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to **NEXIPRAZ OTC** that reduces stomach acid.

**NEXIPRAZ OTC** 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.

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms:

- You lose a lot of weight for no reason.

- You have problems or pain when swallowing.
- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).
- You have severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious 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.
- 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 **NEXIPRAZ OTC**.

Remember to also mention any other ill-effects like pain in your joints.

**Subacute chronic lesions on the skin and mucous membranes:** Proton pump inhibitor medicines, such as **NEXIPRAZ OTC**, 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 OTC**. 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 OTC**, 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.

### **Children**

This medicine should not be used by children under 18 years of age

### **Other medicines and NEXIPRAZ OTC:**

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

Do not take this medicine if you are also taking a medicine containing nelfonavir or atazanavir (used to treat HIV infection) (see **WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEXIPRAZ OTC**).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as other proton pump inhibitors.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- ketoconazole, itraconazole or voriconazole, (used to treat infections caused by fungus) since **NEXIPRAZ OTC** 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 OTC** 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).
- phenytoin (used to treat epilepsy)
- citalopram, imipramine or clomipramine, used to treat depression.
- methotrexate, a chemotherapy medicine used in high doses to treat cancer and rheumatic disorders.
- 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, (*Hypericum perforatum*) used to treat depression.
- cisapride, used for indigestion and heartburn.

### **Pregnancy and breastfeeding**

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 professional for advice before taking **NEXIPRAZ OTC**.

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

### **Driving and using machines**

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

**NEXIPRAZ OTC** contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

### **3. HOW TO TAKE NEXIPRAZ OTC**

Always take **NEXIPRAZ OTC** exactly as described in this leaflet or as your doctor, or pharmacist have told you. You should check with your doctor or pharmacist if you are unsure.

The recommended dose of **NEXIPRAZ OTC** is one tablet a day.

- Do not take more than this recommended dose of one tablet (20 mg) a day, even if you don't feel an improvement immediately.
- The treatment length is up to 14 days.
- When your symptoms have completely gone you should stop taking this medicine.
- If your symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

### **Taking this medicine**

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

### **Alternative method of taking this medicine**

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.

#### **If you take more NEXIPRAZ OTC tablets than you should**

If you take more **NEXIPRAZ OTC** 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 OTC**

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

### **4. POSSIBLE SIDE EFFECTS**

**NEXIPRAZ OTC** can have side effects.

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

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

- Sudden wheezing swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (severe allergic reaction, seen rarely).
- Unusual bleeding or bruising, black, tarry stools; blood in urine or stools; pinpoint red spots on skin.

- 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 seen very rarely.
- Yellow skin, dark urine and tiredness, which can be symptoms of liver problems, seen rarely.
- 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. If you have them, you may have had a serious allergic reaction to **NEXIPRAZ OTC**. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

***Frequent:***

- Headache.
- Effects on your stomach or gut: stomach ache, diarrhoea, wind (flatulence) constipation.
- Feeling sick (nausea) or being sick (vomiting),
- Skin rashes

***Less frequent:***

- Severe diarrhoea characterised by watery stools, stomach pain, fever (Clostridium difficile associated diarrhoea).
- Blood problems such as a reduced number of white blood cells or platelets. This can cause weakness, bruising or make infections more likely (Leukopaenia, thromocytopaenia).
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps

- Dizziness, tingling feelings such as “pins and needles”.
- Trouble in sleeping (insomnia) feeling sleepy.
- Confusion, agitation, depression
- Blurred vision,
- Vertigo (sense of constant movement of self or surroundings),
- Bronchospasm (suddenly feeling wheezy or short of breath),
- Skin rash, lumpy rash (hives) and itchy skin
- Swelling of the feet and ankles
- Dry mouth, taste disturbances, sores in the mouth, thrush.
- Unusual tiredness or weakness.
- Alopecia (Hair loss)
- Joint or muscle pain, muscle weakness
- Increased sweating, impotence, fatigue
- Enlarged breasts in men,
- Changes in blood tests that check how the liver is working, severe liver problems.
- Severe kidney problems.

***Frequency unknown:***

- Low levels of magnesium in the blood. This may cause weakness, being sick (vomiting), cramps, tremor and changes in heart rhythm (arrhythmias). If you have very low levels of magnesium, you may also have low levels of calcium and/or potassium in your blood.
- Hallucinations (seeing, hearing, or feelings things that are not there), aggression.
- Taste disturbances
- Hepatic and renal failure
- Severe liver problems leading to liver failure and inflammation of the brain.

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 OTC**.

## **5. HOW TO STORE NEXIPRAZ OTC**

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 OTC** contains:

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

The other ingredients are crospovidone, diethylphthalate, hydroxypropyl cellulose, hypromellose phthalate, macrogol, microcrystalline cellulose, povidone, sodium stearyl fumarate and film coating material: Opadry brown, polyethylene glycol.

**What NEXIPRAZ OTC looks like and contents of the pack.**

### **NEXIPRAZ OTC**

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

Carton contains 7 or 14 tablets packed in cold form blister strips or desiccant embedded cold form blister strips. Each blister strip contains 7 or 10 tablets.

Ranbaxy Pharmaceuticals (Pty) Ltd  
Esomeprazole 20 mg  
Nexipraz OTC  
Version: August 2023

Gastro-resistant tablets, 20 mg

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

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