

## Patient Information Leaflet

**SCHEDULING STATUS:** S2

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

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

Contains 30 mg sugar per tablet:

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

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## 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.

This medicine is used in adults for the short-term treatment of reflux symptoms such as heartburn and acid regurgitation. Reflux is the backflow of acid from the stomach into the gullet ("foodpipe") which may become inflamed and painful. This may cause you symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

NEXIPRAZ OTC is not meant to bring immediate relief. You may need to take the tablets for 2-3 days in a row before you feel better. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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## 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 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.

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.

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### 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.
- You are aged over 55 years and have new or recently changed reflux symptoms or need to take a non-prescription indigestion or heartburn remedy treatment every day.

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- You have ever had a skin reaction after treatment with a medicine similar to NEXIPRAZ OTC that reduces stomach acid:
  - You are due to have an endoscopy or a urea breath test.
  - You are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease.

- 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.
- 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.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart. If any of the above apply to you (or you are not sure), talk to your doctor straight away.

#### **Children and adolescents**

This medicine should not be used by children and adolescents 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).

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Do not take this medicine if you are also taking a medicine containing nelfnavir or atazanavir (used to treat HIV infection). You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole) or an H<sub>2</sub> antagonist (e.g. ranitidine or famotidine). You may take this medicine with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations of these) if needed.

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

- Ketoconazole and itraconazole (used to treat infections caused by a fungus)
- Voriconazole (used to treat infections caused by a fungus) and clarithromycin (used to treat infections). Your doctor may adjust your dose of NEXIPRAZ OTC if you also have severe liver problems and are treated for a long period of time.
- Erlotinib (used to treat cancer)
- Methotrexate (used to treat cancer and rheumatic disorders)
- Digoxin (used for heart problems)
- Saquinavir (used to treat HIV infection)
- Citalopram, imipramine or clomipramine (used to treat depression)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used to treat epilepsy)
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking NEXIPRAZ OTC
- Cilostazol (used to treat intermittent claudication – a condition where poor blood supply to the leg muscles causes pain and difficulty in walking)
- Cisapride (used for indigestion and heartburn)
- Rifampicin (used to treat tuberculosis)
- Tacrolimus (in cases of organ transplantation)

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- St. John's wort (*Hypericum perforatum*) (used to treat depression)

#### **Pregnancy and breastfeeding**

Do not take **NEXIPRAZ OTC** 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 OTC**.

#### **Driving and using machines**

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

#### **NEXIPRAZ OTC contains sucrose and sodium**

**NEXIPRAZ OTC** contains sugar spheres, which contain sucrose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

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

#### **How much to take**

The recommended dose 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.
- You may need to take the tablets for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

**If you have persistent or longstanding, frequently recurring symptoms even after treatment with this medicine, you should contact your doctor**

### **Taking this medicine**

- You can take your tablet at any time of the day either with food or on an empty stomach.
- Swallow your tablet whole with half a glass of water. Do not chew or crush the tablet. This is because the tablet contains coated pellets, which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets

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

- Put the tablet in a glass of still (non-fizzy) water. Do not use any other liquids.
- Stir until the tablet breaks up (the mixture will not be clear) then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine – do not chew or crush them.

### **If you take more NEXIPRAZ OTC 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 miss several doses, contact your doctor.

## **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:

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- Sudden wheezing, swelling of your lips, tongue and throat, rash, fainting or difficulties in swallowing (severe allergic reaction, seen rarely)
  - 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

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

**Talk to your doctor as soon as possible if you experience any of the following signs of infection:**

This medicine may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

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

Tell your doctor if you notice any of the following:

**Frequent:**

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach ache, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign growths (polyps) in the stomach.

**Less frequent:**

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia), feeling sleepy.
- Dizziness, tingling feelings such as “pins and needles”.
- Spinning feeling (vertigo).

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- Dry mouth.
  - Increased liver enzymes shown in blood tests that check how the liver is working.
  - Skin rash, lumpy rash (hives) and itchy skin.

***Frequency unknown:***

- Blood problems such as a reduced number of white blood cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation on the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.
- Low numbers of red blood cells, white blood cells, and platelets (a condition called pancytopenia)
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness
- Severe kidney problems
- Enlarged breasts in men

- 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.
- Inflammation of the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints

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 REACH 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**

**NEXIPRAZ OTC** Gastro-resistant tablets:

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

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

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**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.

**NEXIPRAZ OTC** is available in pack sizes of 7 and 14 gastro-resistant tablets in blisters. Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Ranbaxy Pharmaceuticals (Pty) Ltd

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