

Approved Patient Information Leaflet for NEXIPRAZ IV

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

NEXIPRAZ IV powder for solution for injection and infusion

NEXIPRAZ IV is sugar free.

Read all of this leaflet carefully before you are given NEXIPRAZ IV

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

What is in this leaflet

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

1. What NEXIPRAZ IV is and what it is used for

NEXIPRAZ IV is used for the short-term treatment (up to 10 days) of gastro-oesophageal reflux disease (GORD) if you are unable to take capsules.

2. What you need to know before you use NEXIPRAZ IV:

NEXIPRAZ IV should not be administered to you:

- If you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles or any of the other ingredients of NEXIPRAZ IV (see **What NEXIPRAZ IV contains**).
- If you are taking medicines containing nelfinavir (used to treat HIV infection) and atazanavir (used to treat and prevent HIV/AIDS).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Special care should be taken with NEXIPRAZ IV:

- If you are suddenly losing weight.
- If you are vomiting regularly.
- If you experience heartburn.
- If you are vomiting blood.
- If you have blood in your faeces.
- If you suspect that you have a stomach ulcer.
- If you have a vitamin deficiency (especially a vitamin B₁₂ deficiency).
- If you develop hypomagnesaemia (fatigue, convulsions, dizziness, abnormal rapid heart rhythms) or if you are taking medicines that can cause hypomagnesaemia (diuretics).
- If you have ever had a skin reaction after treatment with a medicine similar to NEXIPRAZ IV that reduces stomach acid. If you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as possible, as you may need to stop your treatment with NEXIPRAZ IV.
- If you are due to have a specific blood test (Chromogranin A). You should stop taking NEXIPRAZ IV at least 5 days before this blood test.

Taking a proton pump inhibitor like NEXIPRAZ IV, especially over a period of more than one year, increases your risk of fracture of 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).

Proton pump inhibitor medicines, such as NEXIPRAZ IV, may rarely cause interstitial nephritis which is 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 and adolescents

NEXIPRAZ IV should not be used in children.

Other medicines and NEXIPRAZ IV:

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

The following medicines may cause an interaction when used in combination with NEXIPRAZ IV:

- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- Atazanavir, nelfinavir or saquinavir (used to treat HIV-infection).
- Phenytoin (used to treat epilepsy (fits/seizures)).
- Warfarin (used in the prevention of blood clotting formation).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Italoqram, imipramine or clomipramine (used to treat depression).
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Erlotinib (used to treat cancer).
- Digoxin (used for heart problems).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer). If you are taking a high dose of methotrexate, your doctor may temporarily stop your NEXIPRAZ IV

treatment.

- Clopidogrel (used to prevent blood clots).
- Tacrolimus (organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

NEXIPRAZ IV with food and drink and alcohol

NEXIPRAZ IV may be administered with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving NEXIPRAZ IV.

You should not be given NEXIPRAZ IV if you are pregnant or breastfeeding.

Driving and using machines

NEXIPRAZ IV can cause side effects, such as dizziness and blurred vision. Do not drive, operate machinery, or do anything else that requires your attention until you know how NEXIPRAZ IV will affect you.

3. How to use NEXIPRAZ IV

You will not be expected to give yourself NEXIPRAZ IV.

Your doctor or healthcare professional will administer NEXIPRAZ IV to you into a vein (intravenous) or with a drip (infusion) in the hospital for a specific condition.

Your doctor or healthcare professional will make sure you receive the correct dose.

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

If more NEXIPRAZ IV is administered to you than should be:

Since your doctor or healthcare professional will administer NEXIPRAZ IV, he/she will control the dosage and make sure you receive it at the correct time.

4. Possible side effects

NEXIPRAZ IV can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, 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 allergic reaction to NEXIPRAZ IV. 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 frequently occurring:

- Suddenly feeling wheezy or short of breath (bronchospasm).
- Changes in blood tests that check how your liver is working.
- Yellowing of your skin or eyes, dark urine (also called jaundice).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a

high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous eruption).

- Blood problems such as a reduced number of white blood cells, red blood cells or platelets (this can cause weakness, dizziness, rapid heart rate, shortness of breath, pale skin, bruising or make infections more likely).
- Interstitial nephritis (a kidney disorder in which the spaces between the kidney tubules become swollen (inflamed), causing problems with your kidney function).
- Urinary problems (such as changes in the amount of urine).
- Inflammation of pancreas (nausea, vomiting, fever, pain of your stomach area that radiates to your back, increased heart rate).

Frequency unknown:

- Chest pain, changes in the way your heart beats (faster or slower).
- Low levels of magnesium (hypomagnesaemia) causing problems such as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequently occurring:

- Headache.
- Stomach pain, diarrhoea, flatulence, nausea (feeling sick), vomiting (being sick), and constipation.
- Pain and tenderness when you press your stomach or having blood in your stool (fundic gland polyps (benign))
- Pain at the injection site.

Less frequently occurring:

- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Disturbed sleep (insomnia).
- Feeling agitated, confused, depressed, aggressive or having hallucinations (seeing or hearing things that do not exist).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy, feeling tired.
- Taste changes.
- Blurred vision, eye problems.
- Spinning feeling (vertigo), tinnitus (ringing in your ears).
- Dry mouth, inflammation of the inside of the mouth, an infection called “thrush” which can affect the gut and is caused by a fungus.
- Hair loss (temporary).
- Skin rash on exposure to sunshine (photosensitivity).
- Joint pains (arthralgia) or muscle pains (myalgia), back pain.
- Hip, wrist or spine fractures.
- Breast enlargement (in men).
- Inability to develop or maintain an erection during sexual activity (impotence).
- Coughing.

Frequency unknown:

- Unusual weakness or tiredness.
- Increased sweating.
- Severe rash and peeling, similar to psoriasis, mainly in sun-exposed areas such as the neck and forearms (subacute cutaneous lupus erythematosus).
- Inflammation of the colon, or large intestine (watery diarrhoea, cramping).

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, 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 NEXIPRAZ IV.

5. How to store NEXIPRAZ IV:

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Keep vial in outer carton until required for use.
- Vials can be stored exposed to normal in-door light, for up to 24 hours outside the box.

Reconstituted solution for injection and infusion:

- Although chemical and physical stability of reconstituted/diluted solutions has been demonstrated for 12 hours at 30 °C, from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
- Do not use after the expiry date printed on the label or carton.
- For single use only.
- Discard any unused portions.
- 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 NEXIPRAZ IV contains

The active ingredient is esomeprazole. Each vial contains esomeprazole sodium equivalent to 40 mg esomeprazole. The other ingredients are disodium edetate, sodium hydroxide and water for injection.

What NEXIPRAZ IV looks like and contents of the pack

NEXIPRAZ IV: A white to off-white lyophilised cake.

5 ml colourless type I glass vial with 20 mm grey bromobutyl rubber stopper and a grey flip-off aluminium seal.

Pack size: A carton containing 1, 5 or 10 vials.

Holder of Certificate of Registration

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