

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **HETENEX 40 INJECTION**

Dosage form and strength: **Each vial contains esomeprazole sodium 42,5 mg equivalent to 40 mg esomeprazole**

APPROVED PATIENT INFORMATION LEAFLET FOR HETENEX 40 INJECTION

SCHEDULING STATUS

S4

HETENEX 40 INJECTION (powder for solution for injection and infusion)

Esomeprazole sodium

Read all of this leaflet carefully before you are given HETENEX.

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

What is in this leaflet

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

1. What HETENEX is and what it is used for

HETENEX contains a medicine called esomeprazole, it belongs to a group of medicines called 'Proton Pump Inhibitors'. They are used to reduce the amount of acid that your stomach produces. It is used for the short-term treatment (up to 10 days), when you are not able to take your treatment by mouth. It is used for the following conditions:

- Gastro-oesophageal reflux disease (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

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- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

2. What you need to know before you take HETENEX

HETENEX should not be administered to you:

- If you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles or any of the other ingredients of HETENEX (listed in section 6).
- 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:

- 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 stools (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 HETENEX 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 HETENEX.
- If you are due to have a specific blood test (Chromogranin A). You should stop receiving HETENEX at least 5 days before this blood test.

Using a proton pump inhibitor like HETENEX, especially over a period of more than one year, increases your risk

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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).

Children and adolescents

HETENEX should not be used in children.

Other medicines and HETENEX

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

HETENEX can affect the way some medicines work and some medicines can have an effect on HETENEX.

- You must not be given HETENEX if you are taking a medicine containing nelfinavir (used to treat HIV infection) and atazanavir (used to treat and prevent HIV/AIDS)
- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- 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).
- Citalopram, 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 HETENEX treatment.
- Clopidogrel (used to prevent blood clots).
- Tacrolimus (used to prevent rejection after organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

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HETENEX with food, drink and alcohol

HETENEX may be administered with or without food.

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 receiving this medicine. You should not be given HETENEX if you are pregnant or breastfeeding.

Driving and using machines

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

HETENEX contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take HETENEX

You will not be expected to give yourself HETENEX. It will be given to you by a person who is qualified to do so. HETENEX will be administered to you into a vein (intravenous) or with a drip (infusion) in the hospital. This will last for up to 30 minutes.

Use in adults

- HETENEX will be given to you by your doctor who will decide how much you need.
- The recommended dose is 20 mg or 40 mg once a day.
- If you have severe liver problems, the maximum dose is 20 mg a day (GORD).
- The recommended dose for prevention of re-bleeding of gastric or duodenal ulcer, is 80 mg administered as intravenous infusion over 30 minutes followed by a continuous infusion of 8 mg/hr given over 3 days. If you have severe liver problems, a continuous infusion of 4 mg/hr given over 3 days may be sufficient.

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If you take more HETENEX than you should

Since a healthcare provider will administer HETENEX, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take HETENEX

Since a health care provider will administer HETENEX, it is unlikely that the dose will be missed.

4 Possible side effects

HETENEX can have side effects.

Not all side effects reported for HETENEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving HETENEX, please consult your healthcare provider for advice.

If any of the following happens, stop receiving HETENEX 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 HETENEX. 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:

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- 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.

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- Stomach pain, diarrhoea, flatulence, nausea (feeling sick), vomiting (being sick), constipation.
- 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-

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- 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 or pharmacist or nurse. You can also report side effects to SAHPRA via “**6.04 Adverse Drug Reactions Form**”, found online under **SAHPRA’s publications**: <https://www.sahpra.org.za/publications/Index/8/> or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of HETENEX.

5. How to store HETENEX

- Before reconstitution: Store at or below 25 °C. Protect from light.
- Keep vial in outer carton until required for use.
- After reconstitution: The reconstituted solution should be stored at or below 25 ° C and administered within 12 hours after reconstitution with either 0,9 % sodium chloride injection or Ringer’s lactate solution. Administer within 6 hours if 5 % dextrose is used for reconstitution.
- No refrigeration is required.
- Discard any unused solution.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Discard any unused portions.

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- 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 HETENEX contains

Active substance is Esomeprazole sodium.

The other ingredients are:

Disodium edetate, Sodium hydroxide and Water for injection.

What HETENEX looks like and contents of the pack

Before reconstitution: A white to off-white lyophilised cake.

After reconstitution: Clear colourless to pale yellow solution.

HETENEX: 5 ml clear, colourless type I tubular glass vial with 13 mm neck with grey bromobutyl double slotted rubber stopper with a white flip-off seal.

Pack size: 5 or 10 vials.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate

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Registration Application number

54/11.4.3/0281

Access to the corresponding Professional Information

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