PATIENT INFORMATION LEAFLET FOR HEPRALOC 40 IV

SCHEDULING STATUS:

S4

HEPRALOC 40 IV 40 mg per 10 ml vial,

powder for solution for injection

Pantoprazole sodium sesquihydrate

Sugar free

Read all of this leaflet carefully before you are given HEPRALOC 40 IV

- 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.
- **HEPRALOC 40 IV** 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 **HEPRALOC 40 IV** is and what it is used for.
2. What you need to know before you use **HEPRALOC 40 IV.**
3. How to use **HEPRALOC 40 IV.**
4. Possible side effects.
5. How to store **HEPRALOC 40 IV**
6. Contents of the pack and other information

1. What HEPRALOC 40 IV is and what it is used for:

HEPRALOC 40 IV belongs to a group of medicines called proton pump inhibitors, i.e. it inhibits the enzyme which is responsible for gastric acid secretion in the cells of the stomach.

- **HEPRALOC 40 IV** is used for intravenous administration in patients who cannot take their medicine by mouth (swallow).
- **HEPRALOC 40 IV** is used for the short-term treatment of duodenal ulcer (ulcer of the small intestine), stomach ulcer and reflux oesophagitis (inflammation of the gullet, caused by acid reflux).
- If the duodenal ulcer has been demonstrated to be associated with *Helicobacter pylori* infections, **HEPRALOC 40 IV** used in combination with appropriate antibiotics may be useful.
- **HEPRALOC 40 IV** is used for the treatment of Zollinger-Ellison Syndrome (a rare disorder in which there is excessive secretion of gastric juice).

2. What you need to know before you use HEPRALOC 40 IV:

HEPRALOC 40 IV should not be administered to you:

- if you are hypersensitive (allergic) to pantoprazole sodium sesquihydrate or any of the other ingredients of **HEPRALOC 40 IV** (listed in section 6).
- if you your liver does not work properly (and this has been described by your doctor as ‘severe’).
- Safety and efficacy in children have not been established.
- If you are taking a medicine containing atazanavir and nelfinavir (for the treatment of HIV-infection).

If you are unsure about this, ask your doctor.

Warnings and precautions

Special care should be taken with **HEPRALOC 40 IV:**

- **HEPRALOC 40 IV** is only given intravenously. Your doctor or nurse will administer the medicine.
- **HEPRALOC 40 IV** can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.
- If you experience unintentional loss of weight, repeated vomiting, difficulty swallowing, vomiting of blood, if you look pale or and feel weak (anaemia) or if you notice blood in your stool or your stool

appears black. Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole in **HEPRALOC 40 IV** also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Receiving a proton pump inhibitor like **HEPRALOC 40 IV** especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.
- If you have been receiving acid blocking medicines such as **HEPRALOC 40 IV** for longer than 3 years as it may lead to poor absorption of cyanocobalamin.
- If you are on **HEPRALOC 40 IV** for more than three months, it is possible that the level of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- If you experience severe fatigue, joint pain, joint swelling, headaches, a rash on the cheeks and nose, which is called a “butterfly rash”, hair loss, fingers turning white or blue and tingling when cold. These may be a sign of Systemic Lupus Erythematosus which is an autoimmune disease which occurs when the immune system attacks the body because as it may confuse it for something foreign.
- If you experience watery stools, abdominal pain and fever whilst receiving **HEPRALOC 40 IV**. This may be a sign of Clostridium difficile associated diarrhoea (CDAD). You should seek immediate help from a healthcare provider.

Children and adolescents:

HEPRALOC 40 IV is not recommended for use in children as it has not been proven to work in children below 18 years of age.

Other medicines and HEPRALOC 40 IV:

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

HEPRALOC 40 IV can affect the absorption of medicines such as ketoconazole, itraconazole, posaconazole (used to treat fungal infections) and erlotinib (used to treat certain types of cancers) and must not be taken together with atazanavir or nelfinavir (for the treatment of HIV infection) as it can reduce the amount absorbed.

Your response to warfarin may be affected therefore your blood should be monitored when you start or stop receiving **HEPRALOC 40 IV** or if you receive it irregularly.

HEPRALOC 40 IV can affect the concentration levels of medicines such as diazepam (used to treat anxiety, panic attacks and seizures), phenytoin (used to treat seizures), digoxin (used to treat certain types of heart disease), tacrolimus (used in organ transplants), clopidogrel (used to prevent blood clots) and mycophenalate mofetil (used to prevent organ transplant rejection).

HEPRALOC 40 IV can affect the concentration levels of methotrexate (used for the treatment of e.g. certain cancers, psoriasis, arthritis) – if you are receiving a high dose of methotrexate, your doctor may temporarily stop your **HEPRALOC 40 IV** treatment.

Pregnancy and, 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 health care provider for advice before taking this medicine.

Safety during pregnancy and breastfeeding has not been established. Excretion into human milk has been reported.

Driving and using machines:

It is not always possible to predict to what extent **HEPRALOC 40 IV** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HEPRALOC 40 IV** affects them.

Pantoprazole has moderate influence on the ability to drive and use machines.
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

HEPRALOC 40 IV contains:

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml vial, that is to say essentially 'sodium-free'.

3. How to use HEPRALOC 40 IV:

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself **HEPRALOC 40 IV**. It will be given to you by a person who is qualified to do so.

HEPRALOC 40 IV will be prepared by your doctor or nurse by dissolving it in the prescribed solvent. It is given by a single injection. Your doctor will determine the correct dosage for your condition.

The usual dose that is recommended is one vial (40 mg) per day.

HEPRALOC 40 IV is indicated for intravenous administration in patients who cannot be treated orally (by mouth).

HEPRALOC 40 IV may be used for up to 7 days. Treatment should be replaced with the same oral dose (taken by mouth) as soon as you are able to take medicine by mouth (swallow tablets).

Duodenal ulcer (Ulcer of the small intestine):

The recommended dose is 40 mg pantoprazole daily. The total treatment should be 2 to 4 weeks.

Gastric ulcer (Stomach ulcer):

The recommended dose is 40 mg pantoprazole once daily for 4 to 8 weeks.

Reflux oesophagitis (Inflammation of gullet caused acid reflux):

The recommended dose is 40 mg pantoprazole once daily for 4 to 8 weeks.

Zollinger-Ellison syndrome:

For management of Zollinger-Ellison syndrome, you may receive up to 2 vials per day, given twice daily. Depending on your progress, the dosage can be adapted upwards or downwards as needed.

Elderly patients:

No dosage adjustment is needed in the elderly.

Your doctor will tell you how long your treatment with **HEPRALOC 40 IV** will last.

If you have the impression that the effect of **HEPRALOC 40 IV** is too strong or too weak, tell your doctor or pharmacist.

If you are given more HEPRALOC 40 IV than you should:

Since a healthcare provider will administer **HEPRALOC 40 IV**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use HEPRALOC 40 IV:

Since a health care provider will administer **HEPRALOC 40 IV**, it is unlikely that the dose will be missed.

4. Possible side effects:

HEPRALOC 40 IV can have side effects.

Not all side effects reported for **HEPRALOC 40 IV** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HEPRALOC 40 IV**, please consult your health care provider for advice.

If any of the following happens, stop using **HEPRALOC 40 IV** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- erythema multiforme (bull's eye-like lesion on skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to **HEPRALOC 40 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:

- If you lose a lot of weight for no reason and have problems swallowing,
- if you get stomach pain or indigestion,
- jaundice (yellow eyes or skin),
- if you begin to vomit food or blood,
- if you pass black stools (blood-stained faeces),
- if you have watery stools,
- fatigue, painful muscle spasm, confusion, fits, dizziness, and life-threatening irregular heartbeat; these are symptoms of hypomagnesaemia (low magnesium levels),
- fracture of the hip, wrist or spine,
- painful urination and low back pain as these may be symptoms of kidney problems.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- constipation or flatulence.

Less frequent side effects:

- Trouble falling asleep or staying asleep through the night,
- fatigue,
- dizziness,
- disturbances in vision (blurred vision),
- sensation of tingling, burning, pricking, or numbness on your skin,
- confusion, excitement, restlessness, drowsiness,
- seeing, feeling or hearing things that are not there (hallucinations),

- hair loss,
- taste disturbance,
- the inability to achieve or sustain an erection,
- breast development in males,
- increased sweating,
- feeling of general discomfort or uneasiness,
- ringing in the ears,
- Trouble falling asleep or staying asleep through the night,
- fatigue,
- dizziness,
- disturbances in vision (blurred vision),
- sensation of tingling, burning, pricking, or numbness on your skin,
- confusion, excitement, restlessness, drowsiness,
- seeing, feeling or hearing things that are not there (hallucinations),
- hair loss,
- taste disturbance,
- the inability to achieve or sustain an erection,
- breast development in males,
- increased sweating,
- feeling of general discomfort or uneasiness,
- ringing in the ears,

Side effects with an unknown frequency:

- tiny gastric polyps which may present as epigastric pain, nausea, vomiting and weight loss,
- anterior ischemic optic neuropathy which may present as visual loss, malaise, headache, scalp tenderness, jaw pain on mastication, generalised muscle aches and swelling.
- Decrease in the levels of sodium, magnesium, calcium and potassium.

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 the

Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website and 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 **HEPRALOC 40 IV**.

5. How to store HEPRALOC 40 IV:

- Store all medicines out of reach of children.
- Store at or below 25°C.
- Store in the original package or container
- Keep the vial in the outer carton
- Protect from light or moisture

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HEPRALOC 40 IV contains

- The active substance is Pantoprazole sodium sesquihydrate.
- The other ingredients are Disodium Edetate, Sodium Hydroxide & Water for Injection.

What HEPRALOC 40 IV looks like and contents of the pack:

10 R 10 ml clear blow back tubular glass vial, USP Type-I with 20 mm Neck.

Pack style: 1 X 10 ml, 5 X 10 ml, and 10 X 10 ml

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

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74 Waterfall Drive

Midrand

2066

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