SCHEDULING STATUS:

S4

PATIENT INFORMATION LEAFLET

ESOMEPRAZOLE 40 IV CIPLA 40 mg injection

Sugar free

Read all of this leaflet carefully before you are given ESOMEPRAZOLE 40 IV CIPLA:

- **Keep this leaflet, you may need to read it again.**
- **Do not share ESOMEPRAZOLE 40 IV CIPLA with any other person.**
- **If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.**

What is in this leaflet

1. What ESOMEPRAZOLE 40 IV CIPLA is and what it is used for
2. What you need to know before you take ESOMEPRAZOLE 40 IV CIPLA
3. How to take ESOMEPRAZOLE 40 IV CIPLA
4. Possible side effects that you may experience
5. How to store ESOMEPRAZOLE 40 IV CIPLA
6. Contents of the pack and other information

1. What ESOMEPRAZOLE 40 IV CIPLA is and what it is used for

The active ingredient in ESOMEPRAZOLE 40 IV CIPLA is esomeprazole sodium.

Each vial contains esomeprazole sodium, equivalent to esomeprazole 40 mg and disodium edetate (EDTA) as chelating agent.

ESOMEPRAZOLE 40 IV CIPLA belongs to a class of medicines called proton pump inhibitors.

They work by reducing the amount of acid that your stomach produces.

[ROPRIETARY NAME] is given when oral treatment cannot be used and for the shortest possible time. It is used for treatment of gastro-oesophageal reflux disease (GORD), where acid from the stomach escapes into the oesophagus causing pain, inflammation and heartburn. ESOMEPRAZOLE 40 IV CIPLA is also used to treat and prevent recurrence of bleeding ulcers of the stomach or gut.

2. What you need to know before ESOMEPRAZOLE 40 IV CIPLA is administered to you

ESOMEPRAZOLE 40 IV CIPLA should not be administered to you:

- If you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles, or any of the inactive ingredients of ESOMEPRAZOLE 40 IV CIPLA.
- If you are allergic to other proton pump inhibitors
- If you are also taking nelfinavir or atazanavir, for the treatment of HIV infections.

Warnings and precautions

Tell your doctor or healthcare professional before being given ESOMEPRAZOLE 40 IV CIPLA: Special care should be taken with ESOMEPRAZOLE 40 IV CIPLA:

- If you present any alarm symptoms such as repeated vomiting, significant weight loss, vomiting of blood, difficulty in swallowing and black tarry faeces.
- If you develop kidney problem such blood in the urine decreased urine output, contact your doctor immediately (acute interstitial nephritis),
- If you have liver problems, because your healthcare professional may need to adjust the dosage (see **section 3**).
- If you use medicines such as nelfinavir and atazanavir for HIV infection. (see **section 2 – "before ESOMEPRAZOLE 40 IV CIPLA is administered to you"** and **"Using other**

medicines with ESOMEPRAZOLE 40 IV CIPLA").

- If you are taking warfarin for blood thinning, because you will need frequent monitoring.
- If you are known to have reduced ability to absorb vitamin B12 from your gut.
- If you are at risk of osteoporosis, special care should be taken when receiving ESOMEPRAZOLE 40 IV CIPLA in high doses and long-term. ESOMEPRAZOLE 40 IV CIPLA can increase the risk of hip, wrist and spine fractures, especially in elderly patients.

Since ESOMEPRAZOLE 40 IV CIPLA supresses the secretion of stomach acid, you may be more prone to develop infections involving the stomach or gut. Please report to your doctor immediately if you develop large volumes of loose stools, vomiting and stomach cramps, especially in the presence of fever or chills.

When receiving long-term therapy with ESOMEPRAZOLE 40 IV CIPLA your healthcare professional may consider monitoring your magnesium levels. With a decrease in magnesium levels you may develop symptoms such as tiredness, confusion, involuntary contraction of muscles, dizziness, convulsions and abnormal heart rhythm.

If 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 ESOMEPRAZOLE 40 IV CIPLA.

ESOMEPRAZOLE 40 IV CIPLA will be reconstituted by your healthcare professional.

Children

ESOMEPRAZOLE 40 IV CIPLA should not be used in children since no data is available.

Other medicines and ESOMEPRAZOLE 40 IV CIPLA:

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

If you are taking any of the following medicines, please inform your doctor before you receive ESOMEPRAZOLE 40 IV CIPLA:

- Ketoconazole, itraconazole and voriconazole for fungal infections.
- Digoxin for heart problems, you will require monitoring of your digoxin therapy.
- Phenytoin for epilepsy (convulsions).
- Blood thinners, such as warfarin, since you will require more frequent monitoring of your International Normalised Ratio (INR).
- Clopidogrel, used to treat blood clots.
- Methotrexate to suppress the immune system. Your doctor may consider temporarily stopping your ESOMEPRAZOLE 40 IV CIPLA treatment.
- Tacrolimus to suppress the immune function.
- Cilostazol used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply.
- Cisapride for indigestion and heartburn.
- Nelfinavir, atazanavir and saquinavir for treatment of HIV infection.
- Clarithromycin, an antibiotic.
- Rifampicin for treatment of tuberculosis.
- St. John's wort used to treat depression.

ESOMEPRAZOLE 40 IV CIPLA with food and drink

You may receive ESOMEPRAZOLE 40 IV CIPLA without regard to meals.

Pregnancy, breastfeeding and fertility

The safety of ESOMEPRAZOLE 40 IV CIPLA during pregnancy has not been established.

It is not known whether ESOMEPRAZOLE 40 IV CIPLA is excreted in breast milk. You should not receive ESOMEPRAZOLE 40 IV CIPLA while you are breastfeeding your baby.
Studies do not indicate effects with respect to fertility.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given ESOMEPRAZOLE 40 IV CIPLA.

Driving and using machines

ESOMEPRAZOLE 40 IV CIPLA may cause dizziness and blurred vision. You should not drive or use machines if you are affected.

It is not always possible to predict to what extent ESOMEPRAZOLE 40 IV CIPLA 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 ESOMEPRAZOLE 40 IV CIPLA affects them.

3. How to receive ESOMEPRAZOLE 40 IV CIPLA

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

ESOMEPRAZOLE 40 IV CIPLA is a powder for solution for injection and infusion that will be given into one of your veins over a period of time. It is administered to patients who cannot take oral medicines. Your doctor will determine your dosage based on your diagnosis.

You will not be expected to give yourself ESOMEPRAZOLE 40 IV CIPLA. It will be administered to you by a person who is qualified to do so.

Treatment with ESOMEPRAZOLE 40 IV CIPLA usually lasts up to 7 days, after which you may be given oral medicine. The total duration of treatment is dependent on your diagnosis and whether you are able to take oral medicines.

Use of ESOMEPRAZOLE 40 IV CIPLA in patients with kidney problems

Dose adjustment is not necessary in patients with weakened kidney function.

Use of ESOMEPRAZOLE 40 IV CIPLA in patients with liver problems

If you have severe impairment of liver function, your doctor may decide to adjust your dosage.

If you have the impression that the effect of ESOMEPRAZOLE 40 IV CIPLA is too strong or too weak, please speak to your doctor.

If you receive more ESOMEPRAZOLE 40 IV CIPLA than you should

Since a healthcare professional will administer ESOMEPRAZOLE 40 IV CIPLA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of ESOMEPRAZOLE 40 IV CIPLA

Do not receive a double dose to make up for forgotten individual doses.

4. Possible side-effects

ESOMEPRAZOLE 40 IV CIPLA can have side-effects.

Not all side-effects reported for ESOMEPRAZOLE 40 IV CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving

ESOMEPRAZOLE 40 IV CIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking / using ESOMEPRAZOLE 40 IV CIPLA 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’

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

<u>Frequently side effects:</u>

- Swelling of the face, lips, or tongue, shortness of breath, wheezing, hives, or itching.
- Bruising of the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, as these symptoms may be due to abnormal blood cell and platelet counts.
- Seeing or hearing things that are not real.
- Wheezing or tightness of the chest (bronchospasm).
- Yellow discolouration of the skin or whites of the eyes accompanied by loss of appetite, nausea, pain over the liver area and fever, with or without alteration in consciousness, as this may indicate inflammation of the liver.
- Any skin rash with blister formation.

- Cloudy, dark or discoloured urine, reduced frequency of urination, difficulty passing urine, pain over the bladder or kidneys and swelling of the feet, legs or hands.

Other side-effects that you should report to your doctor as soon as possible include:

Less frequent side effects:

- Thrush.
- A combination of nausea and vomiting, headache, confusion, loss of energy, fatigue, muscle weakness, and muscle spasms or cramps, since this may be due to low blood sodium levels.
- Pins and needles.
- Blurred vision.
- Ulcers or sores inside the mouth, or on the lips.
- Any skin rash, itching or hives, including a skin rash in areas exposed to the sun.
- Muscle weakness.
- Pain in the wrist, back, or hip and groin area, with the inability to put weight on the affected limb, as this may be due to a fracture.
- Swelling of the feet or hands.

Frequency unknown:

- Severe stomach pain accompanied by nausea and vomiting, distension of the stomach and fever or chills.
- Muscle weakness, shortness of breath, slow breathing, tiredness, mood changes and irregular heartbeat, as this may be due to low blood levels of potassium.
- Diarrhoea (loose stools); however, if you have severe, foul-smelling diarrhoea, you need to report to your doctor urgently. Rash on your skin, especially in areas exposed to the sun.

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.
- Stomach pain, loose stools, bloating and gas (flatulence), nausea, vomiting and constipation.
- Pain and burning at the injection site.

Less frequent side effects:

- Sleeplessness, agitation, confusion, depression, aggression.
- Dizziness, feeling sleepy or drowsy and taste changes.
- The feeling that your environment is moving or spinning.
- Dry mouth.
- Hair loss.
- Joint pain (arthralgia), muscle pain (myalgia).
- Enlargement of breast tissue in men, impotence (erectile dysfunction).
- Feeling of general discomfort or uneasiness (malaise), excessive sweating (hyperhidrosis).

<u>Frequency unknown:</u>

- Tiredness, involuntary muscle contractions, disorientation, irritability, convulsions, muscle spasms or cramps, dizziness or increased heartrate, as this may be due to low blood levels of magnesium or calcium.
- Loss of coordination (ataxia), anxiety with panic attacks, episodic night terrors, attention deficit.

- Tiredness and fever.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or other healthcare professional.

Reporting of side effects

If you get side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects Via. https://www.sahpra.org.za/Publications/index/8 or to Cipla Medpro (Pty) Ltd. (by e-mail: drugsafetysa@cipla.com). You can furthermore report side 209 effects directly to the marketing authorisation holder via. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ESOMEPRAZOLE 40 IV CIPLA

The centre where you receive treatment will store and dispose of ESOMEPRAZOLE 40 IV CIPLA on your behalf.

Store at or below 30 °C in outer container.

Protect the vial from light. Vials can be stored exposed to normal in-door light, for up to 24 hours outside the box.

Reconstituted solution for injection and infusion:

Chemical in use stability of the reconstituted solution has been demonstrated for 12 hours in 0,9 % sodium chloride solution for intravenous use at 30 °C, however reconstituted solution should be used immediately and any unused portion discarded. 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 fridge (2 – 8 °C).

Store all medicines out of reach of children.

6. Contents of the pack and other information

What ESOMEPRAZOLE 40 IV CIPLA contains

Each vial contains esomeprazole sodium, equivalent to esomeprazole 40 mg and disodium edetate (EDTA) as chelating agent.

Inactive ingredients are disodium edetate and sodium hydroxide

What ESOMEPRAZOLE 40 IV CIPLA looks like and contents of the pack

White to almost white cake in a colourless glass vial.

Type I clear glass vial of 5 mℓ sealed with a dark grey rubber stopper and an aluminium cap with plastic flip-off seal, packaged in a cardboard box, or 10 vials of 5 mℓ in a cardboard box.

Holder of Certificate of Registration

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