PATIENT INFORMATION LEAFLET

TRULOC IV 40 mg powder for solution for injection/infusion

SCHEDULING STATUS

S4

ESOMEPRAZOLE TRULOC IV 40 mg INJECTION

(Esomeprazole 40 mg injection and infusion)

Read all of this leaflet carefully before you are given TRULOC IV 40 mg:

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

1. What TRULOC IV 40 mg is and what it is used for

The active ingredient in TRULOC IV 40 mg is esomeprazole.

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

TRULOC IV 40 mg belongs to a class of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

TRULOC IV 40 mg 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. TRULOC IV 40 mg is also used to treat and prevent recurrence of bleeding ulcers of the stomach or gut.

2. What you need to know before TRULOC IV 40 mg is administered to you

TRULOC IV 40 mg should not be administered to you:

- if you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles, or any of the inactive ingredients of TRULOC IV 40 mg.
- 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 TRULOC IV 40 mg:

Special care should be taken with TRULOC IV 40 mg:

- if you present any alarm symptoms such as repeated vomiting, significant weight loss, vomiting of blood, difficulty in swallowing and black tarry faeces. TRULOC IV 40 mg may affect the kidneys (interstitial nephritis). Inform your doctor if you experience any pain while urinating or lower back pain.
- 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 TRULOC IV 40 mg is administered to you" and "Using other medicines with TRULOC IV 40 mg"**).
- 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 TRULOC

IV 40 mg in high doses and long-term. TRULOC IV 40 mg can increase the risk of hip, wrist and spine fractures, especially in elderly patients.

Since TRULOC IV 40 mg 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 TRULOC IV 40 mg 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 TRULOC IV 40 mg.
TRULOC IV 40 mg should not be used in children.
TRULOC IV 40 mg will be reconstituted by your healthcare professional.

Children:

TRULOC IV 40 mg should not be used in children since no data are available.

Other medicines and TRULOC IV 40 mg:

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 TRULOC IV 40 mg:

- 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 TRULOC IV 40 mg 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, tipranavir and saquinavir for treatment of HIV infection.
- clarithromycin, an antibiotic.
- rifampicin for treatment of tuberculosis.
- St. John's Wort used to treat depression.

TRULOC IV 40 mg with food and drink

You may receive TRULOC IV 40 mg without regard to meals.

Pregnancy, breastfeeding and fertility

The safety of TRULOC IV 40 mg during pregnancy has not been established.

It is not known whether TRULOC IV 40 mg is excreted in breast milk.

You should not receive TRULOC IV 40 mg while you are breastfeeding your baby.

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

Studies do not indicate effects with respect to fertility.

Driving and using machines

TRULOC IV 40 mg 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 TRULOC IV 40 mg 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 TRULOC IV 40 mg affects them.

3. How to receive TRULOC IV 40 mg

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

TRULOC IV 40 mg 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 TRULOC IV 40 mg. It will be administered to you by a person who is qualified to do so.

Treatment with TRULOC IV 40 mg 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 TRULOC IV 40 mg in patients with kidney problems

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

Use of TRULOC IV 40 mg in patients with liver problem

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 TRULOC IV 40 mg is too strong or too weak, please speak to your doctor.

If you receive more TRULOC IV 40 mg than you should

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

If you miss a dose of TRULOC IV 40 mg

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

4. Possible side effects

TRULOC IV 40 mg can have side effects.

Not all side effects reported for TRULOC IV 40 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TRULOC IV 40 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking / using TRULOC IV 40 mg 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 TRULOC IV 40 mg. 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>Frequent 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).

Frequency unknown:

- 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 co-ordination (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 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 TRULOC IV 40 mg.

5. How to store TRULOC IV 40 mg

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the outer container to protect the vials from light.

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

The reconstituted solution should be used immediately however it may be stored for up to 12 hours in 0,9 % sodium chloride solution for intravenous use. The reconstituted solution can be kept in normal indoor light at up to 30 °C.

Do not use after the expiry date stated on the carton. 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 TRULOC IV 40 mg contains

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

The other ingredient is sodium hydroxide (for pH adjustment).

What TRULOC IV 40 mg looks like and contents of the pack

TRULOC IV 40 mg is a white to almost white cake or powder in a colourless glass vial.

TRULOC IV 40 mg powder for solution for injection/infusion is presented in type I clear glass vials of 5 ml and sealed with a dark grey bromobutyl rubber stopper and grey aluminium cap with a grey plastic flip-off seal. The pack sizes are 1 or 10 vials in an outer carton.

Holder of Certificate of Registration

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