TRULOC IV 40 mg

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
TRULOC IV 40 mg, powder for solution for injection/infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 mL vial contains esomeprazole sodium 42,55 mg, equivalent to esomeprazole 40 mg.
One mL provides 8 mg of esomeprazole after reconstitution with 5 mL of 0,9 % sodium chloride for intravenous (IV) use.
Sugar free.
Essentially 'sodium free'.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Powder for solution for injection/infusion.
A white to almost white cake or powder in a colourless glass vial.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
TRULOC IV 40 mg is indicated for:
- the treatment of gastro-oesophageal reflux disease as an alternative where oral therapy is not appropriate and for the shortest possible time
- gastro-oesophageal reflux disease:
  - treatment of erosive reflux oesophagitis
  - long-term management of patients with healed oesophagitis to prevent relapse
  - treatment of severe symptoms of reflux disease
- the short-term maintenance of haemostasis
- the prevention of rebleeding in patients following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

4.2 Posology and method of administration
Posology
Adults:
Gastro-oesophageal reflux disease (GORD)
Treatment with TRULOC IV 40 mg can be given for up to 7 days as part of a full treatment period for the specified indications. When oral therapy is possible or appropriate, intravenous therapy with TRULOC IV 40 mg should be discontinued and the therapy should be continued orally.

Treatment of erosive reflux oesophagitis
40 mg once daily.
The duration of treatment should be 4 weeks. An additional 4 weeks treatment is recommended for patients in whom the oesophagitis has not healed or who have persistent symptoms.

Symptomatic gastro-oesophageal reflux disease (GORD)
If gastro-oesophageal reflux disease (GORD) symptom control has not been achieved after 4 weeks of treatment with the prescribed daily dose, especially where differentiation of diagnosis of GORD with angina and congestive heart failure is present, further investigation is recommended.

Long-term management of patients with healed oesophagitis to prevent relapse and treatment of severe symptoms of reflux disease
20 mg once daily.

Maintenance of haemostasis and prevention of rebleeding of gastric or duodenal ulcers
80 mg administered as bolus infusion over 30 minutes followed by a continuous intravenous infusion of 8 mg/hour given over 3 days.
The parenteral treatment period should be followed by acid-suppression therapy with esomeprazole 40 mg once daily for 4 weeks.

Special populations
Impaired renal function
Dose adjustment is not required in patients with impaired renal function. Due to limited experience in patients with severe renal insufficiency, such patients should be treated with caution.

Impaired hepatic function
Gastro-oesophageal reflux disease (GORD)
Dose adjustment is not required in patients with mild to moderate liver impairment (Child- Pugh Class A, B). For patients with severe liver impairment (Child-Pugh Class C), a maximum daily dose of 20 mg TRULOC IV 40 mg should not be exceeded.

Bleeding ulcers
Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, following an initial bolus dose of 80 mg TRULOC IV 40 mg, a continuous intravenous infusion dose of 4 mg/hour may be sufficient to maintain adequate acid control.

Elderly
Dose adjustment is not required in the elderly.

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

Method of administration
For instructions on reconstitution of the medicine before administration, see section 6.6.

Injection (40 mg vial)
40 mg dose
The reconstituted solution should be given as an intravenous injection over a period of at least 3 minutes.

20 mg dose
Half of the reconstituted solution should be given as an intravenous injection over a period of approximately 3 minutes.

The reconstituted solution for injection is yellow (see section 6.6).

Infusion (40 mg vial)
40 mg dose
The reconstituted solution should be given as an intravenous infusion over a period of 10 - 30 minutes.

20 mg dose
Half of the reconstituted solution should be given as an intravenous infusion over a period of 10 - 30 minutes.

Continuous infusion (40 mg vial)
80 mg bolus dose
The reconstituted solution containing 80 mg esomeprazole should be given as an intravenous infusion over a period of 30 minutes.

8 mg/hour dose
The reconstituted solution should be given as a continuous intravenous infusion over a period of 71,5 hours (calculated rate of infusion of 8 mg/hour).

The reconstituted solution for infusion is yellow (see section 6.6).

4.3 Contraindications
TRULOC IV 40 mg is contraindicated in:
- hypersensitivity to esomeprazole, substituted benzimidazoles or to any of the ingredients of TRULOC IV 40 mg (see section 6.1)
- patients treated concomitantly with nelfinavir or atazanavir (see section 4.5).

4.4 Special warnings and precautions for use
In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with TRULOC IV 40 mg may alleviate symptoms and delay diagnosis.

TRULOC IV 40 mg should be used with caution in hepatic impairment and dose adjustment may be required (see section 4.2).

Concomitant administration with TRULOC IV 40 mg and medicines such as atazanavir and nelfinavir is contraindicated (see sections 4.3 and 4.5).

Therapeutic medicine monitoring is recommended during concomitant treatment with warfarin (see section 4.5).

Occurrence of acute interstitial nephritis
Acute interstitial nephritis has been observed in patients taking proton pump inhibitors (PPIs) including TRULOC IV 40 mg. Acute interstitial nephritis may occur at any point during therapy, which may progress to acute kidney injury and/or chronic renal failure. Discontinue TRULOC IV 40 mg if acute interstitial nephritis develops.

Other effects related to acid inhibition
During treatment with TRULOC IV 40 mg, serum gastrin increases, in response to decreased acid secretion.

During long-term oral treatment with esomeprazole, gastric glandular cysts occur. These changes are a physiological consequence of pronounced inhibition of acid secretion, are benign, and appear to be reversible.

Gastrointestinal infections
Decreased gastric acidity due to any means, including proton pump inhibitors such as TRULOC IV 40 mg, increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with TRULOC IV 40 mg may lead to increased risk of gastrointestinal infections, such as *Salmonella* and *Campylobacter*, *Shigella* and possibly also *Clostridium difficile* in hospitalised patients (see section 4.8).

Absorption of vitamin B12
TRULOC IV 40 mg, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.

Hypomagnesaemia
Severe hypomagnesaemia has been reported in patients treated with proton pump inhibitors (PPIs) like TRULOC IV 40 mg, for at least 3 months, and in most cases for a year.
Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular dysrhythmia can occur, but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI. For patients expected to be on prolonged treatment or who take PPIs, including TRULOC IV 40 mg, with digoxin or medicines that may cause hypomagnesaemia (e.g. diuretics), healthcare professionals should consider measuring magnesium levels before starting TRULOC IV 40 mg treatment and periodically during treatment.

Risk of fractures
Proton pump inhibitors, including TRULOC IV 40 mg, especially if used in high doses and over long duration, may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10 - 40 %. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Subacute cutaneous lupus erythematosus (SCLE)
Proton pump inhibitors are associated with very infrequent cases of subacute cutaneous lupus erythematosus (SCLE). If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the healthcare professional should consider stopping TRULOC IV 40 mg. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

Combination with other medicines
Concomitant administration of clopidogrel and esomeprazole resulted in decreased exposure to the active metabolite of clopidogrel by an average of 40 %. The maximum inhibition of (ADP induced) platelet aggregation decreased by an average of 14 %. Based on these data, concomitant use of TRULOC IV 40 mg and clopidogrel should be avoided.

Co-administration of esomeprazole with atazanavir is not recommended (see section 4.5).
Esomeprazole is a cytochrome P450 2C19 (CYP2C19) inhibitor. When starting or ending treatment with esomeprazole, the potential for interactions with medicines metabolised through CYP2C19 should be considered. An interaction is observed between clopidogrel and esomeprazole (see section 4.5). The clinical relevance of this interaction is uncertain. As a precaution, concomitant use of esomeprazole and clopidogrel should be discouraged.

Interference with laboratory tests
The increased CgA level may interfere with investigations for neuroendocrine tumours. To avoid this interference, the esomeprazole treatment should be temporarily stopped 5 days before CgA measurements.
If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment as in TRULOC IV 40 mg.

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

TRULOC IV 40 mg contains sodium
TRULOC IV 40 mg contains less than 0,023 g sodium per vial, that is to say essentially 'sodium free'.

4.5 Interaction with other medicines and other forms of interaction
Effects of other medicines on the pharmacokinetics of TRULOC IV 40 mg:
Protease inhibitors
Omeprazole has been reported to interact with some protease inhibitors. The clinical importance and the mechanisms behind these reported interactions are not always known. Increased gastric pH during omeprazole treatment may change the absorption of the protease inhibitors. Other possible interaction mechanisms are via inhibition of CYP2C19.

Antiretroviral medicines
Omeprazole has been reported to interact with some antiretroviral medicines. The clinical importance and the mechanisms behind these reported interactions are not always known.
Increased gastric pH during omeprazole treatment may change the absorption of the antiretroviral medicine. Other possible interaction mechanisms are via CYP2C19. For some antiretroviral medicines, such as atazanavir and nelfinavir, decreased serum levels have been reported when given together with omeprazole and concomitant administration is not recommended.

For other antiretroviral medicines, such as saquinavir, increased serum levels have been reported. There are also some antiretroviral medicines for which unchanged serum levels have been reported when given with omeprazole, including darunavir (with concomitant ritonavir), amprenavir (with concomitant ritonavir) and lopinavir (with concomitant ritonavir). Due to the similar pharmacodynamic effects and pharmacokinetic properties of omeprazole and esomeprazole, concomitant administration with TRULOC IV 40 mg and antiretroviral medicines such as atazanavir and nelfinavir is not recommended (see sections 4.3 and 4.4).
Tipranavir may decrease the concentration of TRULOC IV 40 mg. Co-administration is not recommended. However, if used concurrently, the dose of TRULOC IV 40 mg should be increased.

Medicines with pH dependent absorption
Gastric acid suppression during treatment with esomeprazole and other PPIs might decrease or increase the absorption of medicines with a gastric pH dependent absorption. As with other medicines that decrease intragastric acidity, the absorption of medicines such as ketoconazole, itraconazole and erlotinib can decrease and the absorption of digoxin can increase during treatment with TRULOC IV 40 mg.

Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10 % (up to 30 % in two out of ten subjects). Digoxin toxicity has been reported infrequently. However, caution should be exercised when TRULOC IV 40 mg is given at high doses in elderly patients. Therapeutic monitoring of digoxin should then be reinforced.

Medicines metabolised by CYP2C19
Esomeprazole inhibits CYP2C19, the major esomeprazole-metabolising enzyme. Thus, when esomeprazole is combined with medicines metabolised by CYP2C19, such as diazepam, citalopram, imipramine, clomipramine, phenytoin etc., the plasma concentrations of these medicines may be increased and a dose reduction could be needed. No *in vivo* interaction studies have been performed with the high dose intravenous regimen (80 mg+8 mg/h). The effect of esomeprazole on medicines metabolised by CYP2C19 may be more pronounced during this regimen, and patients should be monitored closely for adverse effects, during the 3 day intravenous treatment period.

Diazepam
Esomeprazole inhibits CYP2C19, the major esomeprazole metabolising enzyme. Concomitant oral administration of 30 mg esomeprazole resulted in a 45 % decrease in clearance of the CYP2C19 substrate diazepam. The interaction is unlikely to be of clinical relevance.

Phenytoin
Concomitant oral administration of 40 mg esomeprazole resulted in a 13 % increase in trough plasma levels of phenytoin in epileptic patients; dose adjustment was not required in this study. It is recommended to monitor the plasma concentrations of phenytoin when treatment with TRULOC IV 40 mg is introduced or withdrawn.

Warfarin
Concomitant oral administration of 40 mg esomeprazole to warfarin-treated patients showed that, despite a slight elevation in the trough plasma concentrations of less potent R-isomer of warfarin, the coagulation times were within the accepted range. However, from post-marketed use, cases of elevated international normalised ratio (INR) of clinical significance have been reported during concomitant treatment with warfarin. Close monitoring is recommended when initiating and ending treatment with warfarin or other coumarin derivatives (see section 4.4).

Clopidogrel
Results from studies in healthy subjects have shown a pharmacokinetic/pharmacodynamics interaction between clopidogrel (300 mg loading dose/75 mg daily maintenance dose) and esomeprazole (40 mg orally daily), resulting in decreased exposure to the active metabolite of clopidogrel by an average of 40 % and resulting in decreased maximum inhibition of (adenosine diphosphate (ADP) induced) platelet aggregation by an average of 14 %.

Inconsistent data on the clinical implications of a pharmacokinetic/pharmacodynamic interaction of esomeprazole in terms of major cardiovascular events have been reported from both observational and clinical studies. The use of TRULOC IV 40 mg with clopidogrel should be discouraged.

Methotrexate
When given together with proton pump inhibitors, including TRULOC IV 40 mg, methotrexate levels have been reported to increase in some patients. In high-dose methotrexate administration a temporary withdrawal of TRULOC IV 40 mg may need to be considered.

Tacrolimus
Concomitant administration of TRULOC IV 40 mg has been reported to increase the serum levels of tacrolimus. A reinforced monitoring of tacrolimus concentrations as well as renal function (creatinine clearance) should be performed, and dosage of tacrolimus adjusted if needed.

Cilostazol
Omeprazole as well as esomeprazole act as inhibitors of CYP2C19. Omeprazole given in doses of 40 mg to healthy subjects in a cross-over study, increased maximum peak concentration (C_{max}) and area under the plasma concentration-time curve (AUC) for cilostazol by 18 % and 26 % respectively, and one of its metabolites by 29 % and 69 % respectively.

Cisapride
In healthy volunteers, concomitant oral administration of 40 mg esomeprazole resulted in a 32 % increase in AUC and a 31 % prolongation of elimination half-life ($t_{½}$) but no significant increase in peak plasma levels of cisapride.
This interaction did not alter the influence of cisapride on cardiac electrophysiology.

Medicines which inhibit CYP2C19 and/or CYP3A4
Esomeprazole is metabolised by CYP2C19 and CYP3A4.
Concomitant oral administration of esomeprazole and a CYP3A4 inhibitor, clarithromycin (500 mg twice daily) resulted in a doubling of exposure (AUC) to esomeprazole. Concomitant administration of TRULOC IV 40 mg and a combined inhibitor of CYP2C19 and CYP3A4, such as voriconazole, may result in more than doubling of the esomeprazole exposure.
However, dose adjustment of TRULOC IV 40 mg is not required in either of these situations. A dose adjustment should be considered in patients with severe hepatic impairment and if long-term treatment is indicated.

Medicines which induce CYP2C19 and/or CYP3A4
Medicines known to induce CYP2C19 or CYP3A4 or both (such as rifampicin and St. John's wort) may lead to decreased esomeprazole serum levels by increasing the esomeprazole metabolism.

Investigated medicines with no clinically relevant interaction
Amoxicillin or quinidine
TRULOC IV 40 mg has been shown to have no clinically relevant effects on the pharmacokinetics of amoxicillin or quinidine.

Naproxen or rofecoxib
Studies evaluating concomitant administration of esomeprazole and either naproxen (non-selective nonsteroidal anti-inflammatory drug (NSAID)) or rofecoxib (COX-2-selective NSAID) did not identify any clinically relevant interaction.

Paediatric population
Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation
Pregnancy
Limited clinical data on exposed pregnancies are available for esomeprazole. A moderate amount of data on pregnant women (between 300 - 1000 pregnancy outcomes) indicated no malformative or foeto/neonatal toxicity of esomeprazole. However, caution should be exercised when prescribing TRULOC IV 40 mg to pregnant women.

Breastfeeding
It is not known whether esomeprazole is excreted in human breast milk. No studies in lactating women have been performed. Therefore TRULOC IV 40 mg should not be used during breastfeeding.

Fertility
Animal studies with the racemic mixture omeprazole, given by oral administration, do not indicate effects with respect to fertility.

4.7 Effects on ability to drive and use machines
TRULOC IV 40 mg has minor influence on the ability to drive or use machines. Adverse reactions such as dizziness and blurred vision have been reported less frequently (see section 4.8). If affected, patients should not drive or use machines.

4.8 Undesirable effects
a. Summary of the safety profile
Headache, abdominal pain, diarrhoea and nausea are among those adverse reactions that have been frequently reported.

b. Tabulated summary of adverse reactions
The following adverse reactions have been reported:

System organ class	Frequency	Side effects
Infections and infestations	*Less frequent* *Frequency unknown*	Gastrointestinal candidiasis Enteric infections
Blood and lymphatic system disorders	*Less frequent*	Leucopenia, thrombocytopenia, agranulocytosis, pancytopenia
Immune system disorders	*Less frequent*	Hypersensitivity reactions e.g. angioedema, anaphylactic reaction or shock
Metabolism and nutrition disorders	*Less frequent* *Frequency unknown*	Hyponatraemia Hypomagnesaemia, hypocalcaemia, hypokalaemia, malabsorption (cyanocobalamin, vitamin C and calcium)
Psychiatric disorders	*Less frequent*	Insomnia, agitation, confusion, depression, aggression, hallucination
Nervous system disorders	*Frequent* *Less frequent* *Frequency unknown*	Headache Dizziness, paraesthesia, somnolence, taste disturbance Ataxia, anxiety with panic attacks, episodic night terrors, attention deficit
Eye disorders	*Less frequent*	Blurred vision
Ear and labyrinth disorders	*Less frequent*	Vertigo, tinnitus
Cardiac disorders	*Frequency unknown*	Angina, tachycardia, bradycardia
Respiratory, thoracic and mediastinal disorders	*Less frequent*	Bronchospasm, coughing
Gastrointestinal disorders	*Frequent* *Less frequent* *Frequency unknown*	Abdominal pain, diarrhoea, flatulence, nausea or vomiting, constipation, fundic gland polyps (benign) Dry mouth, stomatitis, gastrointestinal candidiasis Microscopic colitis
Hepatobiliary disorders	*Less frequent*	Increased liver enzymes, hepatitis with or without jaundice, hepatic failure, hepatic encephalopathy
Skin and subcutaneous tissue disorders	*Less frequent* *Frequency unknown*	Dermatitis, pruritus, urticaria, rash, alopecia, photosensitivity, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous eruption, drug reaction with eosinophilia and systemic symptoms (DRESS) Sub-acute cutaneous lupus erythematosus
Musculoskeletal, connective tissue and bone disorders	*Less frequent* *Frequency unknown*	Arthralgia, myalgia, muscular weakness, fracture of the hip, wrist or spine Myopathy
Renal and urinary disorders	*Less frequent*	Interstitial nephritis, may progress to acute kidney injury and/or chronic renal failure, renal failure
Reproductive system and breast disorders	*Less frequent*	Gynaecomastia, impotence
General disorders and administrative site conditions	*Frequent* *Less frequent* *Frequency unknown*	Administration site reactions* Malaise, hyperhidrosis, peripheral oedema Fatigue, fever

* Administration site reactions have mainly been observed in a study with high-dose exposure over 3 days (72 hours). In the non-clinical programme for esomeprazole intravenous formulation there was no evidence of vaso-irritation, but a slight tissue inflammatory reaction at the injection site after subcutaneous (paravenous) injection was noted. The non-clinical findings somewhat indicated that the clinical tissue irritation was concentration related.

c. Description of selected adverse reactions
Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole (the racemate) intravenous injection, especially at high doses, but no causal relationship has been established.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms
The symptoms described in connection with deliberate esomeprazole, as in TRULOC IV 40 mg, overdose (limited experience of oral doses in excess of 240 mg/day) are transient.
Single oral doses of 80 mg and intravenous doses of 308 mg TRULOC IV 40 mg over 24 hours were uneventful.

Management of overdose
No specific antidote is known. Esomeprazole is extensively plasma protein bound and is therefore not readily dialysable. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Drugs for acid-related disorders – proton pump inhibitors
ATC code: A02BC05
Pharmacological classification: A 11.4.3 – Medicines acting on gastrointestinal tract – Other.

Mechanism of action
Esomeprazole, the S-isomer of omeprazole, reduces gastric acid secretion through inhibition of the enzyme H^+K^+-ATPase, the acid pump in the parietal cell, where it is concentrated and converted to the active form in the acidic environment of the secretory canaliculi. Here, it is activated by proton-catalysed formation of a tetracyclic sulfenamide, trapping the medicine so that it cannot diffuse back across the canalicular membrane. The activated form then binds covalently with sulfhydryl groups of cysteines in the H^+K^+-ATPase, irreversibly inactivating the pump molecule. This effect on the final step of the gastric acid secretion is dose-dependent and inhibitory for both basal and stimulated acid secretion.

Acid secretion resumes only after new pump molecules are synthesised and inserted into the luminal membrane, providing a prolonged suppression of acid secretion, despite the much shorter plasma half-life of the parent compound.

Using area under the curve (AUC) as a surrogate parameter for plasma concentration, a relationship between inhibition of acid secretion and exposure has been shown, after oral administration of esomeprazole.

During intravenous administration of 80 mg esomeprazole as a bolus infusion over 30 minutes, followed by a continuous intravenous infusion of 8 mg/hour for 23,5 hours, intragastric pH above 4, and pH above 6 was maintained for a mean time of 21 hours, and 11 - 13 hours, respectively, over 24 hours in healthy subjects.

In a clinical study, following endoscopic haemostasis, patients with bleeding gastric or duodenal ulcers received either 80 mg esomeprazole IV administered as bolus infusion over 30 minutes followed by a continuous infusion of 8 mg/hour or placebo for 72 hours. After the initial 72 hour period, all patients received oral esomeprazole 40 mg for 27 days for acid suppression. The occurrence of rebleeding within 3 days was 5,9 % in the treatment group compared to 10,3 % for the placebo group. At 7- and 30-days post-treatment, the occurrence was 7,2 % vs 12,9 % and 7,7 % vs 13,6 %, respectively.

The 24 hour intragastric pH profile of oral esomeprazole 40 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg and rabeprazole 20 mg once daily was evaluated in symptomatic GORD (gastro-oesophageal reflux disorder) patients. On day 5, intragastric pH was maintained above 4,0 for a mean of 15,3 hours with esomeprazole, 13,3 hours with rabeprazole, 12,9 hours with omeprazole, 12,7 hours with lansoprazole and 11,2 hours with pantoprazole. Esomeprazole also provided a significantly higher percentage of patients with an intragastric pH greater than 4,0 for more than 12 hours relative to the other proton pump inhibitors.

5.2 Pharmacokinetic properties
Distribution:
The apparent volume of distribution at steady state in healthy subjects is approximately 0.22 L/kg body weight.

Plasma protein binding:
Esomeprazole is 97 % plasma protein bound.

Biotransformation:
Esomeprazole is completely metabolised by the cytochrome P450 system (CYP). The major part of the metabolism of esomeprazole is dependent on the polymorphic CYP2C19, responsible for the formation of the hydroxy- and desmethyl metabolites of esomeprazole. The remaining part is dependent on another specific isoform, CYP3A4, responsible for the formation of esomeprazole sulphone, the main metabolite in plasma.

Elimination:
The parameters below reflect mainly the pharmacokinetics in individuals with a functional CYP2C19 enzyme, i.e. extensive metabolisers.

Total plasma clearance is about 17 L/hour after a single dose and about 9 L/hour after repeated administration. The plasma elimination half-life is about 1,3 hours after repeated once-daily dosing. Esomeprazole is completely eliminated from plasma between doses, with no tendency for accumulation during once-daily administration.

The major metabolites of esomeprazole have no effect on gastric acid secretion. Almost 80 % of an oral dose of esomeprazole is excreted as metabolites in the urine, the remainder in the faeces. Less than 1 % of the parent compound is found in urine.

Linearity/non-linearity:
The area under the plasma concentration-time curve increases in a non-linear fashion with repeated administration of esomeprazole.
This increase is dose-dependent and results in a non-linear dose-AUC relationship after repeated administration. This time- and dose-dependency is due to a decrease of first pass metabolism and systemic clearance probably caused by inhibition of the CYP2C19 enzyme by esomeprazole and/or its sulphone metabolite.

Pharmacokinetics in special patient groups
These findings have no implications for the dosing of esomeprazole.

Elderly
The metabolism of esomeprazole is not significantly changed in elderly subjects (71 - 80 years of age).

Gender
Following a single oral dose of 40 mg esomeprazole the mean area under the plasma concentration-time curve is approximately 30 % higher in females than in males. No gender difference is seen after repeated once-daily administration. Similar differences have been seen for intravenous administration of esomeprazole. These findings have no implications for the dosage of esomeprazole.

Renal impairment
No studies have been performed in patients with decreased renal function. Since the kidney is responsible for the excretion of the metabolites of esomeprazole but not for the elimination of the parent compound, the metabolism of esomeprazole is not expected to be changed in patients with impaired renal function.

Hepatic impairment
In patients with severe liver impairment (Child-Pugh C) there is a doubling of the area under the plasma concentration-time curve of esomeprazole. Therefore, a maximum of 20 mg should not be exceeded in GORD patients with severe impairment. For patients with bleeding ulcers and severe liver impairment, following an initial bolus dose of 80 mg, a maximum continuous intravenous infusion dose of 4 mg/hour may be sufficient in patients with bleeding ulcers. Esomeprazole or its major metabolites do not show any tendency to accumulate with once-daily dosing.

5.3 Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Disodium edetate
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities
TRULOC IV 40 mg must not be used with other medicines other than the diluents mentioned in section 6.6.
The degradation of the reconstituted solution is largely dependent on pH and therefore the product should only be prepared with 0,9 % sodium chloride as specified for intravenous use in section 6.6. Reconstituted solution should not be mixed with another medicine and should not be given with another medicine in the same infusion set.

6.3 Shelf life
2 years.

Reconstituted solution for injection and infusion
Ideally, reconstituted solution should be used immediately and any unused portion discarded. Stability of the reconstituted solution has been demonstrated for 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.

6.4 Special precautions for storage
Store at or below 30 °C.
Store in the outer container to protect the vials from light.
Vials can be stored exposed to normal indoor light, for up to 24 hours outside the box.
TRULOC IV 40 mg should be used immediately after reconstitution and any unused portion discarded. If not used immediately, the reconstituted solution should be refrigerated at 2 - 8 °C and used within 24 hours.

6.5 Nature and contents of container
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 aluminium cap with a grey plastic flip-off seal.
The pack sizes are 1 or 10 vials in an outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
The reconstituted solution should be inspected visually for particulate matter and discoloration prior to administration. The reconstituted solution for injection or infusion is yellow (see section 4.2). Only clear solution should be used. For single use only. If the entire reconstituted content of the vial is not required, any unused solution should be disposed of.

Reconstitution instructions
Injection (40 mg vial)
A solution for injection (8 mg/mL) is prepared by adding 5 mL of 0,9 % sodium chloride for intravenous use to the esomeprazole 40 mg vial.

Infusion (40 mg vial)
A solution for infusion is prepared by dissolving the content of one vial of TRULOC IV 40 mg in up to 100 mL of 0,9 % sodium chloride for intravenous use.

Continuous infusion (40 mg vial)
A solution for infusion is prepared by dissolving the content of 2 vials of TRULOC IV 40 mg in up to 100 mL of 0,9 % sodium chloride for intravenous use.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake 7945
Cape Town
South Africa
Tel.: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBER
A48/11.4.3/0120

9. DATE OF FIRST AUTHORISATION
30 November 2021

10. DATE OF REVISION OF THE TEXT
23 September 2025

MOZAMBIQUE
TRULOC IV 40 mg: A6802

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TRULOC IV 40 mg, powder for solution for injection/infusion
Esomeprazole
Sugar free
Essentially 'sodium free'.

Read all of this leaflet carefully before you are given TRULOC IV 40 mg
- 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 healthcare provider.
- TRULOC IV 40 mg 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 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
- 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:
Tell your doctor or healthcare professional before being given the injection if:
- if you are hypersensitive (allergic) to esomeprazole, substituted benzimidazoles or any of the other ingredients of TRULOC IV 40 mg (see section 6)
- if you are allergic to other proton pump inhibitors
- if you are also taking nelfinavir or atazanavir, for the treatment of human immunodeficiency virus (HIV) infections.

Warnings and precautions
Tell your doctor or healthcare professional before being given the injection:
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 human immunodeficiency virus (HIV) infection, (see TRULOC IV 40 mg should not be administered to you, and Other medicines and 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
- if you are due to have a specific blood test (chromogranin A).

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. Remember to also mention any other ill-effects like pain in your joints.

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 provider if you are taking any other medicine. (This includes complementary or 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
- erlotinib, used in cancer treatment
- citalopram, imipramine or clomipramine (used to treat depression)
- diazepam (used to treat anxiety, relax muscles or in epilepsy).

TRULOC IV 40 mg with food and drink
You may receive TRULOC IV 40 mg without regard to meals.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before you are given TRULOC IV 40 mg.

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.
Studies do not indicate effects with respect to fertility.

Driving and using machines
TRULOC IV 40 mg has minor influence on the ability to drive or use 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.

TRULOC IV 40 mg contains sodium
TRULOC IV 40 mg contains less than 0,023 g sodium per vial, that is to say essentially 'sodium free'.

3. How TRULOC IV 40 mg will be given to you
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 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 TRULOC IV 40 mg is too strong or too weak, tell your doctor or pharmacist.

If you are administered 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 overdose.

If you miss a dose of TRULOC IV 40 mg
Do not receive a double dose to make up for forgotten individual doses.
Since a healthcare professional will administer TRULOC IV 40 mg, it is unlikely that the dose will be missed.

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 using TRULOC IV 40 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop 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, 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 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:
- 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
- seeing or hearing things that are not real (hallucinations)
- any skin rash with blister formation, reddening of the skin with blisters or peeling (there may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals), symptoms of Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms
- 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
- 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
- heart disease including tightness or chest pains, slower or increased heart rate.

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, benign polyps (non-cancerous tumours) in the stomach
- pain and burning at the injection site.

Less frequent side effects:
- thrush
- 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
- 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
- sleeplessness, agitation, confusion, depression, aggression
- dizziness, feeling sleepy or drowsy, taste changes, pins and needles
- blurred vision
- the feeling that your environment is moving or spinning, ringing in the ears
- wheezing or tightness of the chest (bronchospasm), coughing
- dry mouth, ulcers or sores inside the mouth, or on the lips, 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, 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), swelling of the feet or hands
- tiredness and fever.

The following side effects have been reported but the frequency for them to occur is not known:
- 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
- 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
- muscle weakness.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of TRULOC IV 40 mg. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

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 indoor 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:
The active substance is esomeprazole sodium.
Each 5 mL vial contains esomeprazole sodium 42,55 mg, 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 aluminium cap with a plastic flip-off seal. The pack sizes are 1 or 10 vials in an outer carton.
Not all pack sizes may be marketed.

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This leaflet was last revised in
23 September 2025

Registration number
A48/11.4.3/0120

MOZAMBIQUE
TRULOC IV 40 mg: A6802

Marketed by:
AFT Pharmaceuticals SA (Pty) Ltd

pharma dynamics

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

TRULOC IV 40 mg, poeier vir oplossing vir inspuiting/infusie
Esomeprasool
Suikervry
Wesenlik 'natriumvry'.

Lees hierdie hele inligtingsblad deeglik deur, voordat TRULOC IV 40 mg aan u toegedien word
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- TRULOC IV 40 mg is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad

1. Wat TRULOC IV 40 mg is en waarvoor dit gebruik word
Die aktiewe bestanddeel in TRULOC IV 40 mg is esomeprasool.
Elke flessie bevat natriumesomeprasool, gelykstaande aan 40 mg esomeprasool en dinatriumedetaat (EDTA) as 'n cheleermiddel.
TRULOC IV 40 mg behoort aan 'n klas medisyne wat protonpomp-inhibeerders genoem word. Dit werk, deur die hoeveelheid suur wat u maag vervaardig, te verminder.
TRULOC IV 40 mg word toegedien oor die kortste moontlike tydperk, wanneer mondelikse behandelingsmetodes nie benut kan word nie.

Dit word gebruik vir die behandeling van:
- gastro-esofageale refluksiekte (GERS), waar suur vanuit die maag in die slukderm vrygestel word en pyn, inflammasie en sooibrand veroorsaak
- om die herhaling van bloeiende ulkusse van die maag of ingewande te behandel en te voorkom.

2. Wat u nodig het om te weet, voordat TRULOC IV 40 mg aan u toegedien word
TRULOC IV 40 mg moet nie aan u toegedien word:
Vertel u dokter of gesondheidsorgdeskundige, voordat die inspuiting aan u toegedien word:
- indien u hipersensitief (allergies) is vir esomeprasool, gesubstitueerde bensimidasole, of enige van die ander bestanddele van TRULOC IV 40 mg nie. (sien afdeling 6)
- indien u allergies is vir ander protonpomp-inhibeerders nie
- indien u ook nelfinavir of atasanavir neem, vir die behandeling van menslike immuniteitsgebreksvirus (MIV) infeksies nie.

Waarskuwings en voorsorgmaatreëls
Vertel u dokter of gesondheidsorgdeskundige, voordat die inspuiting aan u toegedien word:
Spesiale sorg moet geneem word met TRULOC IV 40 mg:
- indien u enige gevaarsimptome, soos herhaalde braking, beduidende gewigsverlies, braking van bloed, slukprobleme en swart teeragtige ontlasting, ervaar
- TRULOC IV 40 mg kan u niere aantas (interstisiële nefritis). U moet u dokter inlig, indien u enige pyn in u lae rug, of pynlike urinering ervaar
- indien u lewerprobleme het, aangesien u gesondheidsorgverskaffer dit nodig mag vind, om die dosering aan te pas (sien afdeling 3)
- indien u medisyne soos nelfinavir en atasanavir vir MIV-infeksie gebruik (sien TRULOC IV 40 mg moet nie aan u toegedien word, en Ander medisyne en TRULOC IV 40 mg)
- indien u warfarien neem vir bloedverdunning, aangesien u gereelde monitering sal benodig
- indien u bewus is dat u 'n verminderde vermoë het om vitamien B12 vanuit u ingewande te absorbeer
- indien u 'n risiko toon vir osteoporose, moet spesiale sorg geneem word wanneer TRULOC IV 40 mg teen hoë dosisse en oor 'n langtermyn, aan u toegedien word. TRULOC IV 40 mg mag die risiko vir heup-, gewrig- en ruggraatfrakture verhoog, veral by bejaarde pasiënte
- indien u binnekort 'n spesifieke bloedtoets moet ondergaan (chromogranien A).

Aangesien TRULOC IV 40 mg die afskeiding van maagsuur onderdruk, mag u meer geneig wees om infeksies van die maag of ingewande te ontwikkel. Besoek asseblief onmiddellik u dokter, indien u groot volumes los stoelgang, braking en maagkrampe ontwikkel, veral in die teenwoordigheid van koors of kouekoors.

Wanneer u langtermyn behandeling met TRULOC IV 40 mg ontvang, mag u gesondheidsorgdeskundige oorweeg om u magnesiumvlakke te monitor. Tydens 'n afname in magnesiumvlakke, mag u simptome soos moegheid, verwarring, onwillekeurige sametrekking van spiere, duiseligheid, konvulsies en abnormale hartritme, ontwikkel.

Indien u 'n uitslag op u vel ontwikkel, veral op gedeeltes wat aan die son blootgestel word, vertel u dokter so gou as moontlik, aangesien u behandeling met TRULOC IV 40 mg gestaak mag word.
Onthou om ook enige ander ongunstige effekte, soos pyn in u gewrigte, te noem.

TRULOC IV 40 mg sal deur u gesondheidsorgdeskundige hersaamgestel word.

Kinders
TRULOC IV 40 mg moet nie deur kinders gebruik word nie, aangesien daar geen data beskikbaar is nie.

Ander medisyne en TRULOC IV 40 mg
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende of tradisionele medisyne in).

Indien u enige van die volgende medisyne neem, stel asseblief u dokter in kennis voordat u TRULOC IV 40 mg ontvang:
- ketokonasool, itrakonasool en vorikonasool, vir swaminfeksies
- digoksien, vir hartprobleme. Monitering van u digoksien behandeling sal benodig word
- fenitoïen vir epilepsie (konvulsies)
- bloedverdunners, soos warfarien, aangesien u meer gereelde monitering van u internasionale normaliserende ratio (INR) sal benodig
- klopidrogel, gebruik om bloedklonte te behandel
- metotreksaat, om die immuunstelsel te onderdruk. U dokter mag oorweeg om u behandeling met TRULOC IV 40 mg tydelik te staak
- takrolimus om die immuunfunksie te onderdruk
- silostasol, gebruik om intermitterende kloudikasie te behandel – pyn in u bene wanneer u loop, wat deur onvoldoende bloedtoevoer veroorsaak word
- sisapried vir slegte spysvertering en sooibrand
- nelfinavir, atasanavir, tipranavir, en sakinavir, vir die behandeling van MIV-infeksie
- klaritromisien ('n antibiotika)
- rifampisien vir die behandeling van tuberkulose
- Johanneskruid (gebruik om depressie te behandel)
- erlonitib (gebruik tydens kankerbehandeling)
- sitalopram. imipramien, of klomipramien (gebruik on depressie te behandel)
- diasepam (gebruik om angs te behandel, spiere te ontspan, of tydens epilepsie).

TRULOC IV 40 mg saam met kos en drinkgoed
U mag TRULOC IV 40 mg ontvang sonder om maaltye in ag te neem.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat TRULOC IV 40 mg aan u toegedien word.

Die veiligheid van TRULOC IV 40 mg tydens swangerskap is nie vasgestel nie.
Dit is nie bekend of TRULOC IV 40 mg in borsmelk uitgeskei word nie. U moet nie TRULOC IV 40 mg ontvang terwyl u u baba borsvoed nie. Navorsing dui nie die effek op vrugbaarheid nie.

Bestuur en die hantering van masjiene
TRULOC IV 40 mg het 'n geringe invloed op die vermoë om te bestuur, of masjiene te hanteer. TRUOC IV 40 mg mag duiseligheid en versteurde visie veroorsaak. U moet nie bestuur of masjinerie hanteer, indien u aangetas word nie.
Dit is nie altyd moontlik om te voorspel tot watter mate TRULOC IV 40 mg met die daaglikse aktiwiteite van 'n pasiënt mag inmeng nie. Pasiënte moet verseker dat hulle nie by die bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is hoe TRULOC IV 40 mg hulle beïnvloed nie.

TRULOC IV 40 mg bevat minder as 0,023 g natrium per flessie, dit is dus wesenlik 'natriumvry'.

3. Hoe TRULOC IV 40 mg aan u toegedien sal word
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

TRULOC IV 40 mg is 'n poeier vir oplossing vir inspuiting en infusie, wat oor 'n spesifieke tydperk, in een van u are toegedien sal word. Dit word toegedien aan pasiënte wie nie orale medisyne kan neem nie. U dokter sal u dosis bepaal op grond van u diagnose.

Daar sal nie van u verwag word om self die toediening van TRULOC IV 40 mg te behartig nie. Dit sal aan u toegedien word deur 'n persoon wat bevoeg is om dit te doen.

Behandeling met TRULOC IV 40 mg duur gewoonlik tot en met 7 dae, waarna mondelikse medisyne aan u toegedien sal word. Die algehele behandelingsduur hang af van u diagnose, en of u in staat is om die medisyne mondeliks te neem.

Gebruik van TRULOC IV 40 mg deur pasiënte met nierprobleme
Doseringsaanpassing is nie nodig by pasiënte met verswakte nierfunksie nie.

Gebruik van TRULOC IV 40 mg deur pasiënte met lewerprobleme
Indien u erge ingekorte lewerfunksie het, mag u dokter besluit om u dosering aan te pas.

Indien u onder die indruk is dat die uitwerking van TRULOC IV 40 mg té sterk, of té swak is, vertel u dokter, of apteker.

Indien u meer TRULOC IV 40 mg ontvang as wat u moes
Aangesien TRULOC IV 40 mg deur 'n gesondheidsorgdeskundige toegedien sal word, sal hy/sy die dosering beheer. In die geval van 'n oordosering, sal u dokter egter die oordosis hanteer.

Indien u 'n dosis TRULOC IV 40 mg oorslaan
Moet nie 'n dubbeldosis ontvang om op te maak vir vergete individuele doserings nie.
Aangesien 'n gesondheidsorgdeskundige TRULOC IV 40 mg sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte
TRULOC IV 40 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir TRULOC IV 40 mg aangemeld is, word in hierdie inligtingsblad genoem nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar terwyl u TRULOC IV 40 mg ontvang, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van TRULOC IV 40 mg en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat asemhaling of sluk mag bemoeilik
- uitslag of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u 'n ernstige allergiese reaksie teenoor TRULOC IV 40 mg ervaar het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- geel verkleuring van die vel of wit gedeeltes van die oë, wat gepaard gaan met aptytverlies, naarheid, pyn oor die leweroppervlakte en koors, met of sonder verandering in bewussynsvlak, aangesien dit 'n aanduiding van lewerinflammasie mag wees
- sien of hoor dinge wat nie werklik is nie (hallusinasies)
- enige veluitslag met blaasvorming, rooi vel met blase, of afskilfering (daar mag ook erge blaasvorming en bloeding van die lippe, oë, mond, neus en geslagsdele, voorkom), simptome van Stevens-Johnson-sindroom, toksiese epidermale nekrolise, of geneesmiddelreaksie met eosinofilie en sistemiese simptome
- troebel, donker of verkleurde urine, minder gereelde urinering, sukkel om te urineer, pyn oor die blaas of niere en swelling van die voete, bene of hande
- pyn in die gewrig, rug, of heup en lies, met die onvermoë om drukking op die aangetaste ledemaat te plaas, aangesien dit die gevolg van 'n fraktuur mag wees
- hartsiekte, insluitend 'n stywe gevoel in die bors, of borspyne, stadiger of vinniger harttempo.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- hoofpyn
- maagpyn, los stoelgang, voel opgeblase en winderigheid (flatulensie), naarheid, braking en konstipasie, benigne poliepe (nie-kankeragtige gewasse) in die maag
- pyn en brandgevoel by die inspuitingsplek.

Minder algemene newe-effekte:
- sproel
- kneusing van die vel, ongewone bloeding, speldpunt rooi kolletjies op die vel, bloeding van die tandvleis, bleek vel, asemnood met inspanning, ongewone moegheid of swakheid, koors en kouekoors, aangesien hierdie simptome te wyte mag wees aan abnormale bloedselle en bloedplaatjietellings
- 'n kombinasie van naarheid en braking, hoofpyn, verwarring, energieverlies, uitputting, spierswakheid, en spierspasmas of krampe, moontlik as gevolg van lae natriumvlakke in die bloed
- slaaploosheid, agitasie, verwarring, depressie, aggressie
- duiseligheid, voel slaperig of lomerig, smaaksteurnisse, spelde en naalde
- wasige sig
- 'n gevoel dat u omgewing draai of beweeg, gelui in die ore
- hyging of benoudheid in die bors (brongospasma), hoes
- droë mond, ulkusse of sere in die mond, of op die lippe, diarree (los stoelgang); indien u egter erge diarree ondervind, wat sleg ruik, moet u dringend by u dokter aanmeld
- veluitslag, veral op gedeeltes wat aan die son blootgestel is, haarverlies
- gewrigspyn (artralgie), spierpyn (mialgie)
- vergroting van borsweefsel by mans, impotensie (erektiele wanfunksie)
- gevoel van algemene ongemak of onrustigheid (malaise), uitermatige gesweet (hiperhidrose), swelling van die hande of voete
- moegheid en koors.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms is onbekend:
- erge maagpyn wat gepaardgaan met naarheid en braking, uitsetting van die maag en koors of kouekoors
- spierswakheid, asemnood, stadige asemhaling, moegheid, gemoedsveranderinge en onreëlmatige hartklop, moontlik as gevolg van lae kaliumvlakke in die bloed
- moegheid, onwillekeurige spiersametrekkings, disoriëntasie, prikkelbaarheid, konvulsies, spierspasmas of -krampe, duiseligheid of verhoogde harttempo, aangesien dit te wyte mag wees aan lae magnesium- of kalsiumbloedvlakke
- verlies van koördinasie (ataksie), angs met paniekaanvalle, episodiese nagvrees, aandaggebrek
- spierswakheid.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem is nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte opmerk, praat met u dokter, apteker, of verpleegkundige. U kan ook newe-effekte by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en elektroniese aanmeldingsplatvorm (who-umc.org), wat op SAHPRA se webtuiste gevind kan word, aanmeld.
Deur newe-effekte aan te meld, kan u help om meer inligting omtrent die veiligheid van TRULOC IV 40 mg in te win. U kan ook 'n e-pos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om TRULOC IV 40 mg te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 30 °C.
Bewaar in die buitenste kartonhouer om die flessies teen lig te beskerm.
Flessies kan blootgestel word aan normale binnenshuise beligting, tot en met 24 uur, buite die kartonhouer.

Die hersaamgestelde oplossing moet onmiddellik gebruik word, maar dit kan egter tot en met 12 uur in 'n 0,9 % natriumchlorieoplossing vir intraveneuse gebruik bewaar word. Die hersaamgestelde oplossing kan in normale binnenshuise beligting tot en met 30 °C gehou word.

Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie. Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat TRULOC IV 40 mg bevat:
Die aktiewe bestanddeel is natriumesomeprasool.
Elke 5 mL flessie bevat 42,55 mg natriumesomeprasool, gelykstaande aan 40 mg esomeprasool en dinatriumedetaat (EDTA) as cheleermiddel.

Die ander bestanddeel is natriumhidroksied (vir pH-aanpassing).

Hoe TRULOC IV 40 mg lyk en die verpakkingsinhoud
TRULOC IV 40 mg is 'n wit tot naaswit klont of poeier in 'n kleurlose glasflessie.

TRULOC IV 40 mg poeier vir oplossing vir inspuiting/infusie word aangebied in 'n tipe I helder 5 mL glasflessie, geseël met 'n donkergrys bromobutiel rubberprop en aluminium doppie, met 'n grys plastiek afskiet-deksel. Die verpakkingshoeveelhede is 1 of 10 flessies in 'n buitenste kartonhouer.
Nie alle verpakkingsgroottes mag bemark word nie.

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Hierdie inligtingsblad was voorheen hersien
23 September 2025

Registrasienommer
A48/11.4.3/0120

MOSAMBIEK
TRULOC IV 40 mg: A6802

Word bemark deur:
AFT Pharmaceuticals SA (Edms.) Bpk.

pharma dynamics