

**PATIENT INFORMATION LEAFLET**  
**TRULOC TABLETS RANGE**

**SCHEDULING STATUS**

S4

**TRULOC 20 and 40 mg** gastro-resistant film coated tablets

Esomeprazole

TRULOC 20 mg: contains sugar - sucrose  $\pm$  12,31 mg and lactose monohydrate 31,875 mg per tablet.

TRULOC 40 mg: contains sugar - sucrose  $\pm$  24,62 mg and lactose monohydrate 63,750 mg per tablet.

**Read all of this leaflet carefully before you start taking TRULOC**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See section 4).

**What is in this leaflet**

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

**1. What is TRULOC and what it is used for**

Esomeprazole, contained in TRULOC, belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used to treat the following conditions:

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- ‘Gastro-oesophageal Reflux Disease’ (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation, and heartburn
- ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called ‘*Helicobacter pylori*’. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- stomach ulcers caused by medicines called NSAIDs (nonsteroidal anti-inflammatory drugs (Medicine)). Esomeprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

## 2. What you need to know before you take TRULOC

### Do not take TRULOC:

- if you are allergic to esomeprazole or any of the other ingredients of TRULOC
- if you are allergic to other “proton pump inhibitors”
- if you are taking medication for HIV treatment (atazanavir or nelfinavir).

### Warnings and precautions

Tell your doctor or healthcare provider before taking TRULOC:

- if you have been experiencing indigestion
- if you have been on continuous medication for longer than a year
- if you have been taking a medication that contains clopidogrel (used in the treatment of blood clots)
- if you are due to have a specific blood test (Chromogranin A)
- if you have had previous intestinal conditions

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- if you develop severe diarrhoea that has watery stools, abdominal pain and fever
- if you are taking TRULOC when necessary and your symptoms change
- if you have a vitamin B<sub>12</sub> deficiency
- if you develop tiredness dizziness, tremor and muscle problems (hypomagnesaemia)
- if you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones
- if you develop kidney problems such as cloudy urine, pain in the kidney area, blood or pus in the urine, frequent urination
- if you develop 'butterfly rash' with sensitivity to sun light (subacute cutaneous lupus erythematosus).

If any of these applies to you, tell your doctor or nurse before you are given TRULOC.

### **Children**

TRULOC should not be used in children younger than 1 year.

### **Other medicines and TRULOC**

Always tell your healthcare provider if you are taking any other medicine.

It is particularly important that you mention the following:

- itraconazole, ketoconazole, voriconazole - used in the treatment of fungal infections
- diazepam - used in the treatment of anxiety
- medicines used to prevent fitting (phenytoin)
- medicines used to prevent blood clotting (warfarin or clopidogrel)
- medicine used to help the symptoms of intermittent claudication (cilostazol)
- medicines used to speed up stomach emptying (cisapride)
- digoxin - used in the treatment of heart problems

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- rifampicin - used for the treatment of Tuberculosis
- st. John's Wort - used to treat depression, or certain type of anti-malignancy medicines (such as erlotinib or another anti-malignancy medicine from the same class)
- TRULOC should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as TRULOC may reduce the blood levels of your antiretroviral medicine
- tipranavir – used to treat HIV
- clarithromycin, an antibiotic
- tacrolimus used to prevent organ transplant rejection
- if you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), TRULOC may need to be temporarily withdrawn.

#### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. You should not take TRULOC if you are pregnant or breastfeeding your baby.

#### **Driving and using machines**

TRULOC may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

#### **TRULOC contains sugar in the form of sucrose and lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take TRULOC**

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

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Always take TRULOC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses are given below:

#### **Adults & Adolescents (12 – 18 years):**

- *Gastro-oesophageal Reflux Disease (GORD):*
  - to treat an inflamed food pipe caused by Gastro-oesophageal Reflux Disease (GORD):  
40 mg once daily for 4 weeks
  - long-term management of patients with healed inflammation: 20 mg once daily
- *patients requiring continued NSAID (nonsteroidal anti-inflammatory drugs) therapy*
  - to prevent stomach ulcers if you are taking NSAIDs: 20 mg or 40 mg once daily
- *eradication of Helicobacter pylori and healing of Helicobacter pylori associated ulcers:*
  - 20 mg TRULOC with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days
- *to treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome)*
  - the recommended initial dosage is 40 mg twice daily. The dosage should then be individually adjusted, and treatment continued as long as clinically indicated.

#### **If you take more TRULOC than you should**

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

#### **If you forget to take TRULOC**

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

If it is almost time for your next dose, do not take the missed dose, and just take the next dose on time.

**4. Possible side effects**

TRULOC can have side effects.

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

If any of the following happens, stop taking/using TRULOC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction)
- rash or itching in the form of reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens Johnson syndrome' or 'toxic epidermal necrolysis'
- yellow skin, dark urine and tiredness which can be symptoms of liver problems.

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

- tightening of chest accompanied with severe coughing (bronchospasm)
- loss or decreased vision
- abdominal swelling (may be an indication of liver failure)

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- excessive sweating
- blood in the urine (nephritis)
- significant reduction in the amount of urine with shortness of breath (this could be a sign of kidney failure).

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*

- stomach pain
- diarrhoea
- nausea/vomiting
- constipation
- headache.

*Less frequent side effects*

- muscle weakness/pain, fracture of the hips, wrists or spine, joint pain
- fever
- development of breast tissue in males
- hair loss
- dry mouth
- inflammation of the mouth and lips
- dizziness
- Blurred vision
- tingling sensation
- loss of balance

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- taste disturbance
- sleepiness
- inability to sleep
- confusion
- depression
- agitation
- hallucination
- low white blood cell count.

*Side effects of which is frequency is unknown*

- Decreased levels of calcium
- Decreased levels of magnesium
- “Butterfly rash” that lasts hours – days.

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 any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TRULOC. You can also send an email directly to the company, [pharmacovigilance@pharmadynamics.co.za](mailto:pharmacovigilance@pharmadynamics.co.za) to ensure safety of the product.

**5. How to store TRULOC**

**Store all medicines out of reach of children.**

Store in original package in order to protect from light and moisture.



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Do not use after the expiry date stated on the label.

Store at or below 25 °C.

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 contains**

The active substance is: TRULOC 20 mg: Each tablet contains 20 mg esomeprazole equivalent to 22,26 mg esomeprazole magnesium. TRULOC 40 mg: Each tablet contains 40 mg esomeprazole equivalent to 44,53 mg esomeprazole magnesium.

The other ingredients are:

*Tablet cores*

Copovidone (K28), crospovidone (Type A), diethyl phthalate, ethyl cellulose, hypromellose, macrogol 8000, magnesium oxide, magnesium stearate, maize starch, methacrylic acid - ethyl acrylate copolymer dispersion (consist of methacrylic acid - ethyl acrylate copolymer, sodium lauryl sulphate, polysorbate 80), povidone, povidone K90, silica colloidal anhydrous, silicified microcrystalline cellulose (Prosolv HD 90) (consist of cellulose microcrystalline and silica colloidal anhydrous), starlac (consist of lactose monohydrate and maize starch), sugar spheres (consist of maize, starch and sucrose), talc.

*Film coating*

Hypromellose, macrogol 8000, talc, titanium dioxide (E171), silica colloidal anhydrous, ferric oxide red (E172).

*Printing ink*

Opacode S-1-17823 black ink: ammonium hydroxide (E527), iron oxide black (E172), isopropyl

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Opacode S-1-17823 black ink: ammonium hydroxide (E527), iron oxide black (E172), isopropyl alcohol, n-butyl alcohol, propylene glycol (E1520), shelac glaze.

#### **What TRULOC looks like and contents of the pack**

TRULOC GR 20 mg: Brick red coloured, round shape, biconvex, film coated tablets, imprinted with "20" on one side with black ink and plain on the other side.

TRULOC GR 40 mg: Brick red coloured, round shape, bevelled edge, biconvex, film coated tablets, imprinted with "40" on one side with black ink and plain on the other side.

14's pack: 2 x Alu/Alu blister packs containing 7 tablets each, packed in a printed outer carton.

28's pack: 4 x Alu/Alu blister packs containing 7 tablets each, packed in a printed outer carton.

30's pack: 2 x Alu/Alu blister packs containing 15 tablets each, packed in a printed outer carton.

60's pack: 4 x Alu/Alu blister packs containing 15 tablets each, packed in a printed outer carton.

90's pack: 6 x Alu/Alu blister packs containing 15 tablets each, packed in a printed outer carton.

*Not all pack sizes will be marketed.*

#### **Holder of Certificate of Registration**

Pharma Dynamics (Pty) Ltd

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#### **Registration numbers**

Truloc 20 mg: A47/11.4.3/0320

Truloc 40 mg: A47/11/4/3/0321

<https://www.mydynamics.co.za/>