PATIENT INFORMATION LEAFLET

TRULOC RANGE

SCHEDULING STATUS:

S4

TRULOC 20 mg gastro-resistant film coated tablets

TRULOC 40 mg gastro-resistant film coated tablets

Esomeprazole

TRULOC 20 mg: contains sugar (sucrose ± 12,31 mg and lactose monohydrate 31,875 mg per tablet).

TRULOC 40 mg: contains sugar (sucrose ± 24,62 mg and lactose monohydrate 63,750 mg per tablet).

Essentially 'sodium free'.

Read all of this leaflet carefully before you start taking TRULOC

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

PATIENT INFORMATION LEAFLET

TRULOC RANGE

1. What TRULOC is 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.

TRULOC is used to treat the following conditions:

- '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 hypersensitive (allergic) to esomeprazole or any of the other ingredients of TRULOC (see section 6)
- if you are taking medication for human immunodeficiency virus (HIV) treatment (atazanavir or nelfinavir).

Warnings and precautions

Take special care with 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
- 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 B12 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).

TRULOC may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking TRULOC or while you are taking it, talk to your doctor straight away:

- if you lose a lot of weight for no reason and have problems swallowing
- if you get stomach pain or indigestion
- if you begin to vomit food or blood
- if you pass black stools (blood-stained faeces).

Serious skin rashes, which can be fatal, have occurred in patients taking TRULOC (see also section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache, body ache. The rash may cover large parts of the body with blistering and peeling of the skin. If at any time during the treatment (even after several weeks) you develop a rash or any of these skin symptoms, stop taking this

medicine and contact your doctor immediately.

Children

There is no experience with TRULOC in children younger than 12 years.

Other medicines and TRULOC

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

It is particularly important that you mention the following medicines:

- itraconazole, ketoconazole, voriconazole – used in the treatment of fungal infections
- diazepam – used in the treatment of anxiety
- phenytoin – used to prevent fitting
- warfarin or clopidogrel – used to prevent blood clotting
- cilostazol – used to help the symptoms of intermittent claudication
- cisapride –used to speed up stomach emptying
- digoxin – used in the treatment of heart problems
- 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 a 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, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using TRULOC.

You should not take TRULOC if you are pregnant or breastfeeding your baby.

Driving and using machines

TRULOC has minor influence on the ability to drive and use machines.

TRULOC may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery. It is not always possible to predict to what extent TRULOC 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 affects them.

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 TRULOC.

TRULOC contains sodium

TRULOC contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium free'.

3. How to take TRULOC

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

Always take/use TRULOC exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended doses are given below:

Adults & adolescents (12 - 18 years):

The usual dose is

- *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
- *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.

The safety and efficacy of TRULOC in children younger than 12 years of age has not been established. No data is available.

Your doctor will tell you how long your treatment with TRULOC will last.
If you have the impression that the effect of TRULOC is too strong or too weak, tell your doctor or pharmacist.

If you take more TRULOC than you should

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

If you forget to take TRULOC

If you forget to take TRULOC, take as soon as you remember, then continue to take TRULOC at the usual times. Do not take a double dose to make up for forgotten individual doses.

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

If any of the following happens, stop using TRULOC 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. 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:

- 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 ‘erythema multiforme’, ‘Stevens-Johnson syndrome’, ‘toxic epidermal necrolysis’ or ‘drug reaction with eosinophilia and systemic symptoms’
- yellow skin, dark urine and tiredness which can be symptoms of liver problems
- tightening of chest accompanied with severe coughing (bronchospasm)
- loss or decreased vision
- abdominal swelling (may be an indication of liver failure)
- 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
- taste disturbance
- sleepiness, inability to sleep

- confusion, depression, agitation, hallucination
- low white blood cell count.

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

- decreased levels of calcium
- decreased levels of magnesium
- “butterfly rash” that lasts hours to 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 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. 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

Store all medicines out of reach of children.

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

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

Store at or below 25 °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 contains:

The active substance is:

TRULOC 20 mg: esomeprazole magnesium equivalent to esomeprazole 20 mg.

TRULOC 40 mg: esomeprazole magnesium equivalent to esomeprazole 40 mg.

The other ingredients are:

Tablet cores

Colloidal silica anhydrous, copovidone, crospovidone, diethyl phthalate, ethyl cellulose, hypromellose, light magnesium oxide, magnesium stearate, macrogol, methacrylic acid-ethyl acrylate copolymer dispersion (consist of methacrylic acid-ethyl acrylate copolymer, sodium lauryl sulphate, polysorbate), povidone, 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, talc, titanium dioxide, silica colloidal anhydrous, ferric oxide red.

Printing ink

Opacode S-1-17823 black ink.

What TRULOC looks like and contents of the pack

TRULOC 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 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.

Alu/Alu blister packs containing 14, 28, 30, 60, or 90 tablets each, packed in a printed outer carton.

Not all pack sizes will be marketed.

Holder of 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)

This leaflet was last revised in

13 November 2024

Registration number(s)

TRULOC 20 mg: A47/11.4.3/0320

TRULOC 40 mg: A47/11.4.3/0321