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SCHEDULING STATUS

S2

TRULOC OTC gastro-resistant film coated tablets Esomeprazole

Contains sugar (sucrose ± 12,31 mg and lactose monohydrate 31,875 mg per tablet).

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

TRULOC OTC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use TRULOC OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TRULOC OTC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.''

What is in this leaflet

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- **What TRULOC OTC is and what it is used for**

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

  This medicine is used in adults for short-term treatment of reflux symptoms such as heartburn and acid regurgitation. Reflux is the backflow of acid from the stomach into the gullet (swollen) the tube connecting your mouth and stomach “foodpipe”) which may become inflamed and painful. This may cause your symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation). TRULOC OTC is not meant to bring immediate relief. You may need to take the tablets for 2- 3 days in a row before you feel better. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What you need to know before you take TRULOC OTC Do not take TRULOC OTC:

- if you are hypersensitive (allergic) to esomeprazole, or any of the other ingredients of TRULOC OTC (listed in section 6)

- if you are taking medication for HIV treatment (atazanavir or nelfinavir)
- as a prevention against heartburn and indigestion long-term.

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Warnings and precautions

Tell your doctor before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another more serious disease.

- you are losing a lot of weight for no reason
- you have ongoing vomiting or vomiting blood (which appears as dark coffee grounds in your vomit)
  - you have difficulty swallowing
- you pass black/dark stools
- if you suspect you have a stomach ulcer, previously had a stomach ulcer or surgery of your stomach or intestines
- if you have continually been on treatment to relieve the symptoms of indigestion or heartburn for 4 or more weeks
- if you have jaundice (yellowing of the skin and eyes) or severe liver disease
- if you are over the age of 55 years and you experience new symptoms, or the symptoms have changed recently, or you are taking any non- prescription medicine or remedies for indigestion or heartburn
- if you have long-term recurring symptoms of indigestion or heartburn you should see your doctor at regular intervals
- if you are having a procedure called an endoscopy or a urea breath test (test to identify if you have a type of bacteria that infects the stomach)
- if you take a product called warfarin (used to treat blood clots)
- 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 develop severe persistent diarrhoea that has watery stools, abdominal pain and fever
- if you have a vitamin B_{12} deficiency
- if blood test results show you have low sodium and magnesium blood levels
- if blood test results show you have decreased levels of calcium, potassium and magnesium
- if you are on TRULOC OTC for more than three months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, confusion, fits, dizziness, or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to lower potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium
- 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 a ‘butterfly rash’ with sensitivity to sun light (subacute cutaneous lupus erythematosus).

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

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Children and adolescents

TRULOC OTC should not be used in children or adolescents below the age of 18 years.

Other medicines and TRULOC OTC

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

It is particularly important that you mention the following:

- itraconazole, ketoconazole, voriconazole – used in the treatment of fungal infections
- erlotinib – used to treat cancer
- diazepam – used in the treatment of anxiety
- phenytoin – used to prevent fits
- 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 (angina)
- 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 OTC should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as TRULOC OTC may reduce the blood levels of your antiretroviral medicine
- saquinavir – 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 OTC may need to be temporarily withdrawn.

Truloc OTC with food and drink

Truloc OTC may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. You should not take TRULOC OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

TRULOC OTC 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 OTC may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TRULOC OTC affects you.

TRULOC OTC 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.

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- **How to take TRULOC OTC**

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

  Always take TRULOC OTC exactly described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

  The usual dose is:

  One tablet TRULOC OTC (20 mg) per day with liquid. Do not chew or crush the tablets.

  It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. The duration of treatment is up to 2 weeks. Once complete relief of symptoms has occurred, treatment should be discontinued.

  If no symptom relief is obtained within 2 weeks of continuous treatment, you should consult a doctor.

  If you take more TRULOC OTC than you should

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

  If you forget to take TRULOC OTC

  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.

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Possible side effects

TRULOC OTC can have side effects.

Not all side effects reported for TRULOC OTC are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking TRULOC OTC, please consult your healthcare provider for advice.

If any of the following happens, stop taking TRULOC OTC 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.

These are all very serious side effects. If you have them, you may have had an allergic serious reaction to TRULOC OTC. 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 ‘Stevens Johnson syndrome’ or ‘toxic epidermal necrolysis’
- skin sores or rash due to a disease called Subacute cutaneous lupus erythematosus
- yellow skin, dark urine and tiredness which can be symptoms of liver problems, abdominal swelling (may be an indication of liver failure)

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- tightening of chest accompanied with severe coughing (bronchospasm)
- loss or decreased vision 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

- headache
- stomach pain, diarrhoea, nausea, vomiting, constipation

Less frequent side effects

- muscle weakness/pain, fracture of the hips, wrists or spine, joint pain
- development of breast tissue in males
- skin inflammation, itching, hives, rash, hair loss, sensitivity to light
- dry mouth, inflammation of the mouth and lips
- dizziness
- tingling sensation
- loss of balance - the sensation that you, or the environment around you, is moving or spinning
- taste disturbance
- strong desire for sleep and feeling of drowsiness inability to sleep, confusion, depression, agitation, hallucination

- low white blood cell or platelet count
- low sodium and magnesium blood levels, vit B12 not absorbing well when ingested, higher liver enzyme
- general discomfort, excessive sweating.

Side effects of which is frequency is unknown

- blood test results showing decreased levels of calcium, potassium and magnesium
- bull's eye lesions/rash
- low levels of white blood cells called neutrophils
- low levels of red blood cells, white blood cells and platelets.

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 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 OTC.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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How to store TRULOC OTC

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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information What TRULOC OTC contains

The active substance is esomeprazole 20 mg equivalent to esomeprazole magnesium 22,26 mg.

The other ingredients are:

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, 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.

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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 alcohol, n-butyl alcohol, propylene glycol (E1520), shellac glaze.

What TRULOC OTC looks like and contents of the pack

Brick red coloured, round shape, biconvex, film coated tablets, imprinted with “20” on one side with black ink and plain on the other side.

Alu/Alu blister packs containing 14 tablets each, packed in a printed outer carton.

Holder of Certificate of Registration

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