

PRODUCT NAME	DESIGN STYLE	ART WORK SIZE	DATE	COUNTRY : South Africa	LOCATION : Chhatral	REMARK :	Supersedes A/W No.:	Department	Name	Signature	Date
ITEM / PACK	DESIGN STYLE	ART WORK SIZE	DATE	Truloc	Chhatral	REMARK :		Activities	Prepared By	Reviewed By	Approved By
CODE	xxxxxxx-6513	S/S	05-04-2025	Truloc	Chhatral	REMARK :		Pkg.Dev	Pkg.Dev	Quality	
DIMENSIONS (MM)	150 x 600 mm			Truloc	Chhatral	REMARK :					
PANTONE SHADE NOS.	Black			Truloc	Chhatral	REMARK :					
NO. OF COLORS: 1				Truloc	Chhatral	REMARK :					
Truloc	Insert	Front/Back		Truloc	Chhatral	REMARK :					
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PATIENT INFORMATION LEAFLET SCHEDULING STATUS [54] TRULOC 20 mg gastro-resistant film coated tablets TRULOC 40 mg gastro-resistant film coated tablets Esomazeprole TRULOC 20 mg contains esomazeprole 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. - You may 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 - What TRULOC is and what it is used for - How to take TRULOC - Possible side effects - How to store TRULOC - Contents of the pack and other information 1. What TRULOC is and what it is used for Esomazeprole, contained in TRULOC, belongs to a group of medicines called 'anxiolytic' inhibitors. They work by reducing the amount of acid that your stomach produces. TRULOC is used to treat the following conditions: - gastro-esophageal reflux disease (GERD); this is a condition where the stomach escapes into the gullet the tube which connects your throat to your stomach) - heartburn, inflammation and healing of the stomach - ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called 'Helicobacter pylori'; 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 (medicines)). Esomazeprole 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 esomazeprole or any of the other ingredients of TRULOC (see section 6) - If you are taking medication for human immunodeficiency virus (HIV) treatment (zalcitabine or nevirapine). Warnings and precautions Talk special care with TRULOC. - If you have been taking long-term indigestion. - If you have been on continuous medication for longer than a year - If you have been taking a medication that contains cimetidine (used in the treatment of blood clots) if you are due to have a specific blood test (prothrombin time) - If you have had previous intestinal conditions - If you develop severe diarrhoea that has watery stools, abdominal pain and fever, your symptoms may be severe - If you are taking TRULOC when necessary and your symptoms change - If you have a vitamin B12 deficiency - If you develop feverish, dizziness, tremor and muscle problems (hypomagnesaemia) - If you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones - Esophageal and/or gastric esophageal reflux disease, 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 have to vomit for blood - If you pass black stools (blood-stained faeces). Serious skin rashes, which can be fatal, have occurred in patients taking TRULOC (see section 4). The rash can be a part of the disease called toxic epidermal necrolysis and conjunctivitis (red and swollen eyes). These serious skin rashes often come after flu-like symptoms such as fever, headache and chills. The rash can spread to 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 any one 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 to your doctor: - itraconazole, ketoconazole, voriconazole – used in the treatment of fungal infections - disodium – used in the treatment of anxiety - phenytoin – used to prevent fitting - warfarin or cimetidine – used to prevent blood clotting - cimetidine – used to help the symptoms of intermittent claudication 3. How to take TRULOC Take one or two tablets twice a day with food. 4. Possible side effects Not all side effects reported for TRULOC are included in this leaflet. Should your general health worsen, or if you experience any of the following symptoms, stop taking TRULOC, please consult your doctor, pharmacist or other healthcare professional for advice. If any of the following happens, stop using TRULOC and contact 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 - fever - if you have any very serious side effects. If you have them, you may have had a serious allergic reaction to TRULOC. You 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 eyes, mouth, nose and genitals. - This could be 'symptoms of severe allergic reaction', 'toxic epidermal necrolysis' or 'drug reaction with eosinophilia and systemic symptoms' - yellow skin, dark urine and tiredness which can be a sign of liver problems - lightening of chest accompanied with severe coughing - dark urine These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TRULOC. You 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. 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