

Rectocare[®]

Nitroglycerin 0.4% Ointment

COMPOSITION

Each gram of ointment contains Nitroglycerin USP 4 mg.

PHARMACOLOGY

The principal pharmacologic action of glyceryl trinitrate is mediated via the release of nitric oxide. When glyceryl trinitrate ointment is applied by the intra-anal route, the internal anal sphincter becomes relaxed. Hypertonicity of the internal but not the external anal sphincter is a predisposing factor in the formation of anal fissures. The blood vessels to the anoderm course through the Internal Anal Sphincter (IAS). Therefore hypertonicity of the IAS may thereby decrease blood flow and cause ischaemia to this region. Distension of the rectum results in the anorector inhibitory reflex and relaxation of the internal anal sphincter. The nerves mediating this reflex lie in the wall of the gut. Release of the neurotransmitter NO from nerves of this type play a significant role in the physiology of the internal anal sphincter. Specifically, NO mediates the anorector inhibitory reflex in man, relaxing the IAS.

INDICATIONS

For relief of pain associated with chronic anal fissure.

DOSAGE & ADMINISTRATION

Nitroglycerin 0.4% ointment should be inserted into the anal cavity with an applicator. The ointment must be inserted at least 1cm into the anus. The dose is to be applied intraanally every twelve hours. Treatment may be continued until the pain abates, up to a maximum of 8 weeks.

ADVERSE EFFECTS

Headache and dizziness is a common side effect experienced with Nitroglycerin 0.4% ointment. A possible side effect is reduced control over bowel movements and leaking of bowel motions although this is expected to be a rare event.

CONTRAINDICATION

Nitroglycerin 0.4% ointment is contraindicated in patients with known hypersensitivity to Nitroglycerin or other ingredients of the formulation.

PRECAUTION & WARNING

Nitroglycerin 0.4% ointment should be used with caution in patients who have severe hepatic or renal disease. It should not be used if patient suffers from severe anemia, glaucoma, hypotension, increased intracranial pressure.

USE IN SPECIAL POPULATION

Pregnancy: There are no adequate data from the use of Nitroglycerin in pregnant women. Animal studies are inconclusive with respect to effects on pregnancy embryonal/foetal parturition and postnatal development. This ointment should not be used during pregnancy. Nursing Mothers: It is not known whether Nitroglycerin is excreted in human milk. Due to the potential harmful effects on the breast fed child, the use of this ointment is not recommended during breast feeding.

Pediatric Use: It is not recommended for use in children and adolescents below 18 years of age due to lack of data on safety and efficacy.

OVERDOSE

Accidental overdose may result in hypotension and reflex tachycardia. Because the hypotension associated with nitroglycerin overdose is the result of venodilation and arterial hypovolaemia, prudent therapy in this situation should be directed toward increasing central fluid volume. Excessive dosage may also give rise to methaemoglobinaemia. This should be treated with methylene blue infusion.

STORAGE

Store below 25°C. Do not freeze. Keep all medicines out of reach of the children.

HOW SUPPLIED

Rectocare[®] Ointment: Each pack contains a tube of 15 gm ointment and an applicator.