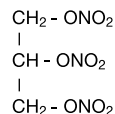


PRODUCT INFORMATION
RECTOGESIC®
(0.2% w/w Glyceryl Trinitrate Ointment)

Rectogesic® contains the active ingredient Glyceryl trinitrate 0.2% w/w in a smooth light amber ointment formulation for topical application. The other ingredients in Rectogesic® are Paraffin-soft yellow; Paraffin liquid; wool fat; ethanol and water-potable.

DESCRIPTION

Glyceryl trinitrate (CAS:53-63-0) is a pale yellow oily liquid. It is slightly soluble in water, soluble in methyl alcohol, ethanol, carbon disulphide, ether and glacial acetic acid. Its chemical name is 1,2,3 - propanetriol trinitrate with empirical formula: C₃H₅N₃O₉ and molecular weight: 227.09. It has the following structural formula:



ACTIONS

Anal fissure is an ischaemic ulcer of the anal mucosa, caused by hypertonicity of the internal anal sphincter (IAS). The most common site is the posterior midline of the anal canal. Nitric oxide has been shown as an important inhibitory neurotransmitter in the IAS. Organic nitrates are degraded by cellular metabolism, releasing nitric oxide. Glyceryl trinitrate ointment releases nitric oxide, and if applied to the anal mucosa causes a fall in maximum anal resting pressure due to relaxation of the internal anal sphincter muscle, amounting to a reversible 'chemical sphincterotomy'.

INDICATIONS

For the treatment of anal fissure and relief of the symptoms associated with anal fissure.

CONTRAINDICATIONS

Severe anaemia, glaucoma, pregnancy lactation, hypotension, increased intracranial pressure and idiosyncrasy to glyceryl trinitrate.

Glyceryl trinitrate should not be coadministered with Viagra™ (sildenafil citrate) and or other Phosphodiesterase Type 5 (PDE5) Inhibitors as this may potentiate the hypotensive effects of organic nitrates.

WARNING

Concurrent treatment with Rectogesic® for anal fissure and anti-anginal products containing nitrates, may interfere with "drug holiday" dosage arrangements for the anti-anginal drug.

PRECAUTIONS

Use in pregnancy (Category B2).

The safety of Rectogesic® in pregnancy has not been established. Therefore Rectogesic® should not be given to pregnant women - see contraindications.

Use in lactation

It is not known whether glyceryl trinitrate is excreted in human milk. Therefore Rectogesic® should not be given to lactating women - see contraindications.

Effect on ability to drive or operate machinery

As patients may experience faintness and/or dizziness, particularly the elderly, reaction time when driving or operating machinery may be impaired especially at the start of treatment.

Use in children

The safety and effectiveness of glyceryl trinitrate in children have not been established.

Interaction with other drugs

Concomitant use of alcohol may enhance vascular effects.

Concomitant use with other nitrates

If a patient is already using glyceryl trinitrate or other nitrates for Cardiac disease then using Rectogesic® could potentially cause tachyphylaxis by eliminating the night time free interval.

Where such tachyphylaxis may cause concern it is advised that Rectogesic® should be used during the day only.

ADVERSE REACTIONS

Headache is the most common reaction to treatment with glyceryl trinitrate. These are usually mild and usually occur after the first few applications only. In a small number of patients headaches may be severe or persist. If headaches persist the dose should be reduced (see OVERDOSAGE). If the headaches continue to occur or are severe, treatment should be withdrawn. Rectogesic® may also cause fainting or dizziness, particularly in the elderly.

Incontinence is also a possible adverse reaction, although this has not been reported to date, and should be completely reversible on withdrawal of the drug.

DOSAGE AND ADMINISTRATION

Adults

Insert a 1 to 1.5 cm strip of ointment (see measurement on box) into the anal canal, either with the finger or an applicator.

Apply the ointment 3 times daily and do not exceed this dosage.

Close the tube tightly, immediately after each use.

Use in children

Safety and effectiveness in children have not been established.

OVERDOSAGE

Headache, fainting or dizziness are the most common indication of overdosage. When these symptoms are observed, treatment should cease for a minimum of 8 hours and then the dosage halved. Simple analgesics such as paracetamol may be helpful for headaches. If headaches are severe and persist, cease administration.

PRESENTATION

30g tube.

STORAGE

Store below 25°C.

POISON SCHEDULE

S3

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