

# New Zealand Data Sheet

## RECTOGESIC<sup>®</sup>

### *0.2% w/w Glyceryl Trinitrate Ointment*

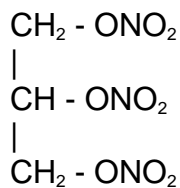
RECTOGESIC contains the active ingredient Glyceryl Trinitrate 0.2% w/w in a smooth light amber ointment formulation for topical application. The other ingredients in RECTOGESIC are alcohol, lanolin, liquid paraffin and yellow soft paraffin.

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## PRESENTATION

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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:  $C_3H_5N_3O_9$  and molecular weight: 227.09. It has the following structural formula:



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## USES

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### ***Indications:***

For the treatment of anal fissure and relief of the symptoms associated with anal fissure. May assist in relief of pain and discomfort associated with haemorrhoids and haemorrhoidectomy.

### ***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'.

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## CONTRAINDICATIONS

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

Glyceryl trinitrate should not be coadministered with Viagra™ (sildenafil citrate), Cialis (tadalafil), Levitra (vardenafil) which are used to treat erectile dysfunction and/or other Phosphodiesterase Type 5 (PDE5) Inhibitors as this may potentiate the hypotensive effects of organic nitrates.

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## WARNING

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

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## PRECAUTIONS

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### ***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.

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## INTERACTIONS

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Concomitant use of alcohol may enhance vascular effects.

Use with Viagra™ (sildenafil citrate), Cialis (tadalafil), Levitra (vardenafil) which are used to treat erectile dysfunction may potentiate the hypotensive effects of glyceryl trinitrate. Please see contraindications.

### ***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.

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## **ADVERSE REACTIONS**

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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.

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## **DOSAGE AND ADMINISTRATION**

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### ***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. This product is intended for Adults Only.

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## **OVERDOSAGE**

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Headache, fainting or dizziness are the most common indication of overdose.

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.

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## **PHARMACEUTICAL PRECAUTIONS**

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RECTOGESIC shelf life is 36 months when stored at or below 25°C.

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## **MEDICINE CLASSIFICATION**

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Pharmacy Only Medicine

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## **PACK SIZE**

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30g aluminium tubes

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## **NAME AND ADDRESS**

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Pharmacy Retailing (NZ) Ltd  
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54 Carbine Road  
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Auckland NEW ZEALAND

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## **DATE OF PREPERATION**

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22<sup>nd</sup> August 2011