

Rectogesic[®]

ointment

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CONSUMER MEDICINE INFORMATION

Please read this leaflet carefully before you start using Rectogesic[®] and keep it for your reference as you may need to read it again. This leaflet is designed to provide you with important information about Rectogesic. Please ask your doctor or pharmacist if you want to know more about Rectogesic. Please tell your doctor at your next visit that you are using Rectogesic.

What is Rectogesic?

Rectogesic Ointment contains 0.2% glyceryl trinitrate in a base of liquid paraffin, soft yellow paraffin, lanolin and ethanol. It is used for the treatment and relief of symptoms of anal fissure and to relieve pain and discomfort and assist in wound healing following haemorrhoid surgery. It is available in a 15g tube and 30g tube.

How will it help me?

If you suffer anal fissure (which has been diagnosed by your doctor), Rectogesic is used as a treatment to help reduce the fissure and relieve the pain and spasm (muscle contraction) associated with this condition.

If you are having haemorrhoid surgery, Rectogesic will relieve your pain and discomfort and assist in wound healing.

Before using Rectogesic?

Before you begin using Rectogesic, you should be aware of some precautions associated with the use of Rectogesic.

Use in children

Rectogesic is not recommended for use in children or in adolescents under 18 years of age.

Precautions

You should not use Rectogesic if you suffer from:

- severe anaemia (low blood count)
- glaucoma (increased eye pressure)
- hypotension (low blood pressure)
- increased intracranial pressure (high pressure inside your head)

Also you should not use Rectogesic if you are pregnant or breastfeeding or if you are allergic to glyceryl trinitrate or any of the other ingredients in Rectogesic.

Use with other medicines

You should not use Rectogesic if you are taking Viagra (sildenafil), Cialis (tadalafil) or Levitra (vardenafil).

Advise your doctor if you are already taking any medication for chest pain or the treatment of any other heart condition. If you are taking oral nitrate products (such as glyceryl trinitrate, isosorbide mononitrate or isosorbide dinitrate) or using glyceryl trinitrate patches, you should not use Rectogesic unless advised to do so by your doctor. The doctor may need to adjust the dose of Rectogesic and advise you on arrangements for a daily 'nitrate-free period' that suits both medications. Discuss this with your doctor and he will advise you as to what you should do.

Driving or operating machinery

Rectogesic may cause dizziness, light headedness, blurred vision, headaches or tiredness in some patients, especially when you first start to use it. Be careful driving a car or operating machinery until you know how Rectogesic affects you.

Interaction with alcohol

Be careful when drinking alcohol while you are using Rectogesic as your blood pressure may drop, making you feel dizzy and faint. Therefore, it is advisable to reduce or stop alcohol consumption during treatment with Rectogesic.

How do I use Rectogesic

Because Rectogesic contains glyceryl trinitrate it must be used strictly as directed. **A 1cm to 1.5cm strip of ointment** (see measurement indicated on box) should be inserted into the anal canal with your finger. The finger may be wrapped in Gladwrap. An applicator is not recommended since it is difficult to judge the amount being squeezed into the anal passage. The ointment must be inserted at least 1cm into the anus. Apply the ointment three times daily and do not exceed the dosage. Wash hands after use.

You should ensure that you have a period of 12 hours each day where you do not use Rectogesic. This is necessary to avoid tolerance (that is, to maintain the full effect of the medication). For example, you could use the ointment at 8am, 2pm and 8pm – this would give you a full 12 hours from 8pm to 8am without the medicine. Talk to your doctor or pharmacist if you need advice on this point.

If the tube is difficult to squeeze – soften the ointment by warming the tube between your hands or in a glass of lukewarm water.

Unwanted effects

You should report any unwanted effects associated with the use of Rectogesic to your doctor or pharmacist, even if the undesirable effect is not mentioned in this leaflet. Some of the more common side effects expected with Rectogesic are listed below.

Headache is a common side effect experienced with Rectogesic. These are usually mild and occur after the first few applications only, due to intolerance to the Rectogesic. The headache may be relieved with a simple analgesic, such as paracetamol.

After applying Rectogesic, you may also experience fainting effect or dizziness, particularly if you are an older person. Changing position slowly from lying or sitting to standing up may help you to avoid this problem. A possible effect is reduced control over your bowel movements and leaking of bowel motions although this is expected to be a rare event and has not been reported to date.

If you experience any of these unwanted effects, do not use any more ointment for at least eight hours, then continue treatment by reducing the amount of ointment by half. If the effect persists, stop the treatment and see your doctor. If anal bleeding increases, stop treatment and tell your doctor.

In case of overdose

Overdosage may occur if you use too much ointment or if you are sensitive to the effects of Rectogesic. Some signs of overdosage are headache, fainting or dizziness. When these symptoms are experienced, you should stop using Rectogesic for at least 8 hours and then resume use with half the dosage. Simple analgesics such as paracetamol may provide temporary relief of headaches. If any of these symptoms persist, stop using Rectogesic and consult your doctor.

Storage conditions

Close the tube tightly, immediately after each use. Store the Rectogesic in a cool place (below 25°C) and protect it from light (e.g. store in a cupboard, not in the bathroom). Keep it where children cannot reach it.

There will be an expiry date (month, year) on the Rectogesic container. The ointment should not be used after this date and should be returned to your pharmacy for disposal.

Sponsor

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