Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.

If you get any side effects chat to your doctor or pharmacist. This includes side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Rectogesic is and why it is used for
2. What you need to know before you use Rectogesic
3. How to use Rectogesic
4. Possible side effects
5. How to store Rectogesic
6. Contents of the pack and other information

1. WHAT RECTOGESIC IS AND WHAT IT IS USED FOR

Rectogesic is a rectal ointment which contains the active substance glyceryl trinitrate. Glyceryl trinitrate belongs to a group of medicines called organic nitrates. The ointment will help to relieve the symptom of pain caused by chronic anal fissures. An anal fissure is a tear in the skin lining the anal canal. Topical application of glyceryl trinitrate to the anal canal reduces the anal pressure and increases the blood flow, thereby reducing pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RECTOGESIC

Do not use Rectogesic:

- if you are allergic to glyceryl trinitrate or to similar medicines
- if you are allergic to any of the other ingredients in the product (listed in section 6)
- if you suffer from heart disease
- if you suffer from heart or blood vessel disorders
- if you suffer from closed-angle glaucoma – a condition where pressure inside the eye rises rapidly causing loss of vision
- if you suffer from migraine or recurrent headaches
- if you suffer from increased intraocular pressure or high pressure within your skull (e.g. head injury or cerebral haemorrhage – bleeding from a ruptured blood vessel in the brain that can be fatal without prompt medical treatment. Close monitoring of your blood pressure (commonly referred to as a ‘blood pressure’ or ‘hypertension’) may be required). This product also contains propylene glycol which may cause skin irritation.
- if you are taking any of the following medicines for erectile dysfunction such as sildenafil (sil-tad-en) or ‘Viagra’, vardenafil (var-den-a-fi-l), or tadalafil (ta-da-fil), or ‘Cialis’ or ‘Adcirca’ among others. Glyceryl trinitrate (glyceryl trinitrate) belongs to a group of medicines called organic nitrates. Rectogesic 4 mg/g Rectal Ointment is for Rectal Use. This medicinal product contains lanolin (wool fat) which may cause a skin reaction (e.g. contact dermatitis). The product also contains propylene glycol which may cause skin irritation.

Method of Administration

3. HOW TO USE RECTOGESIC

A finger covering, such as cling film or a finger cot, may be placed on the finger to be used to apply the ointment. Finger cots can be obtained from your local pharmacy or surgical supplies retailer, or cling film tape. Take special care with Rectogesic:

- if you are allergic to clove oil or cherry laurel
- if you are to be given heparin (blood thinning), monitoring of your blood will be required as your dose of heparin may need to be altered. Please discuss with your doctor before stopping Rectogesic
- if you also have haemorrhoids (piles) and notice more bleeding than usual, you should stop using Rectogesic and discuss this with your doctor
- if you get severe headaches when using Rectogesic, please tell your doctor. Your doctor will decide if you need to use a different amount of Rectogesic, or stop using it completely.

Rectogesic may lower your blood pressure. When getting up from a lying or sitting position, you should get up slowly, otherwise you might feel faint. Your blood pressure is more likely to be lowered if you drink alcohol while you are using Rectogesic.

Children and adolescents

Rectogesic is not suitable for children and adolescents under the age of 18 years because it has not been assessed in people in this age group.

Other medicines and Rectogesic

Rectogesic with alcohol

Rectogesic may lower your blood pressure. When getting up from a lying or sitting position, you should get up slowly, otherwise you might feel faint. Your blood pressure is more likely to be lowered if you drink alcohol while you are using Rectogesic.

Other medicines

• Medicines for depression (tricyclic anti-depressants), acetylcysteine or alteplase
• Medicines for erectile dysfunction such as sildenafil (sil-tad-en) or ‘Viagra’, vardenafil (var-den-a-fi-l), or tadalafil (ta-da-fil), or ‘Cialis’ or ‘Adcirca’ among others
• Medicines for hypotension (diuretics)
• Medicines used to treat heart problems (isosorbide dinitrate, amyl or butyl nitrite; medicines for high blood pressure or depression (tricyclic anti-depressants), acetylcysteine or alteplase

Other medicines and Rectogesic

• Medicines for high blood pressure
• Medicines for depression (tricyclic anti-depressants), acetylcysteine or alteplase
• Medicines for erectile dysfunction such as sildenafil (sil-tad-en) or ‘Viagra’, vardenafil (var-den-a-fi-l), or tadalafil (ta-da-fil), or ‘Cialis’ or ‘Adcirca’ among others
• Medicines for hypotension (diuretics)
• Medicines used to treat heart problems (isosorbide dinitrate, amyl or butyl nitrite)

As Rectogesic contains glyceryl trinitrate, you must tell your doctor or pharmacist if you are using any of the other medicines below before you start using Rectogesic.

Other medicines

• Medicines for high blood pressure
• Medicines for depression (tricyclic anti-depressants), acetylcysteine or alteplase
• Medicines for erectile dysfunction such as sildenafil (sil-tad-en) or ‘Viagra’, vardenafil (var-den-a-fi-l), or tadalafil (ta-da-fil), or ‘Cialis’ or ‘Adcirca’ among others
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• Medicines for hypotension (diuretics)
• Medicines used to treat heart problems (isosorbide dinitrate, amyl or butyl nitrite)
If you use more Rectogesic than you should
If you may have used more ointment than you should you may feel dizzy and light-headed. You may also have fast heart beats or palpitations. If you feel these symptoms wipe away any extra ointment and then talk to your doctor or pharmacist immediately.

If you forget to apply Rectogesic
Do not use a double dose to make up for a forgotten dose. Apply the next dose at the usual time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:
- Anaphylactoid reaction (allergic reaction, potentially fatal with face, lip, tongue or throat swelling, difficulty breathing, shortness of breath or collapse). If you experience any of these symptoms stop using the ointment immediately and seek medical attention.
- Allergic skin reactions (potentially severe). If you have an allergic skin reaction stop using the ointment and seek medical attention immediately.

Other side effects:

Very Common (may affect more than 1 in 10 people)
- Headaches, which may be severe. If you develop a headache as a side effect, wipe off any ointment. If the headaches are unpleasant, you may need to ask your doctor whether you should stop using the medicine.
- Dizziness

Common (may affect up to 1 in 10 people)
- Nausea

Uncommon (may affect up to 1 in 100 people)
- Dizziness
- Vomiting
- Rectal bleeding, rectal disorder
- Anal discomfort, itching or burning of the anal canal
- Fast heart beat or palpitations

Rare (may affect up to 1 in 1,000 people)
- Painfulness on standing up

Other known side effects associated with glyceryl trinitrate products (frequency unknown)
- Flushing
- Unstable angina (chest pain)
- High blood pressure on starting treatment
- Methaemoglobinemia (symptoms are blue/purple colouration of the skin and shortness of breath)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme
HPRA Pharmacovigilance
Website: www.mhra.gov.uk/yellowcard
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rectogesic contains
The active substance is glyceryl trinitrate. One gram of rectal ointment contains 4 mg glyceryl trinitrate. Approximately 1.5 mg glyceryl trinitrate is contained in the usual 375 mg dose of Rectogesic.

The other ingredients are: propylene glycol, lanolin, sorbitan sesquioleate, hard paraffin and white soft paraffin.

What Rectogesic looks like and contents of the pack
Rectogesic is an off-white smooth opaque rectal ointment supplied in 30 g aluminium tubes.