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, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet. See section 4.

What is this in a leaflet:

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 liver or kidney disease
- if you suffer from increased intracranial 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 attention. Cerebral haemorrhage is commonly referred to as a type of stroke) or inadequate cerebral circulation (low volume of blood circulation within your brain)
- if you suffer from anaemia (low iron content in your blood)
- if you suffer from heart or blood vessel disorders
- if you suffer from low blood pressure
- if you suffer from high blood pressure or depression (tricyclic anti-depressants), acetylecysteine or alteplase
- if you are taking or have recently taken any other medicines obtained without a prescription. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines
- if you are allergic to any of the following medicines for erectile dysfunction such as sildenafil citrate, tadalafil, vardenafil; medicines for angina or heart pain such as glyceryl trinitrate (GTN), sotobose dinitrate, amyl or butyl nitrite; medicines for high blood pressure or depression (tricyclic anti-depressants), acetylecysteine or alteplase
- if you are taking any of the following medicines for erectile dysfunction (e.g. contact dermatitis). The product also contains propylene glycol which may cause skin irritation.
- if you are allergic to any of the other ingredients in the product (listed in section 6)
- if you suffer from high blood pressure
- if you suffer from heart or blood vessel disorders
- if you suffer from low blood pressure
- if you suffer from high blood pressure or depression (tricyclic anti-depressants), acetylecysteine or alteplase
- if you are taking or have recently taken any other medicines obtained without a prescription.

Other medicines and Rectogesic

- Medicines for angina or heart pain such as glyceryl trinitrate (GTN), isosorbide dinitrate, amyl or butyl nitrite; medicines for high blood pressure or depression (tricyclic anti-depressants), acetylecysteine or alteplase
- Medicines used to treat heart problems (isosorbide dinitrate and amyl or butyl-nitrite)
- Medicines for high blood pressure
- Diuretics (“water tablets”)
- Medicines used to treat heart problems (isosorbide dinitrate and amyl or butyl-nitrite)
- Other medicines

Take special care with Rectogesic:

- if you suffer from liver or kidney disease
- if you are to be given heparin, close 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 whilst you are using Rectogesic.
- Be careful about drinking alcohol as the ointment may affect you more than usual.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription. Other medicines might alter the therapeutic effect of Rectogesic.

The following medicines or dosages may influence the blood pressure lowering effect of Rectogesic:

- Medicines for erectile dysfunction (male impotence) (sildenafil citrate, tadalafil, vardenafil)
- Medicines for depression (tricyclic anti-depressants)
- Medicines used to treat heart problems (isosorbide dinitrate and amyl or butyl-nitrite)
- Diuretics (“water tablets”)
- Medicines used to treat heart problems (isosorbide dinitrate and amyl or butyl-nitrite)
- Other medicines

Acetylcysteine may increase the effect of Rectogesic on blood flow
- The effect of heparin (used to control blood clotting) may be decreased when used with Rectogesic
- The effect of alteplase (used to treat heart problems) may be decreased when given at the same time as Rectogesic
- Taking Rectogesic with dihydroergotamine (used to treat migraine) may increase the action of dihydroergotamine and lead to coronary vasoconstriction (narrowing of blood vessels in the heart causing slower blood flow)
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (certain types of painkillers) might alter the therapeutic effect of Rectogesic

Rectogesic with alcohol

Be careful about drinking alcohol as the ointment may affect you more than usual.

Pregnancy and breast-feeding

You should not use Rectogesic during pregnancy or when breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant or breast feeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed with Rectogesic 4 mg/g Rectal Ointment. If you feel dizzy, sleepy or have blurred vision when you start to use the ointment, do not drive or work machinery until these effects have worn off.

Rectogesic contains lanolin and propylene glycol

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

- Headaches, which may be severe. If you develop a headache as a side effect, wipe off any

Very Common (may affect more than 1 in 10 people)

Other Side Effects:

- Diarrhoea
- Vomiting
- Rectal bleeding, rectal disorder
- Anal fissures, pain or bleeding of the anal canal
- Fast heart beat or palpitations

Rare (may affect up to 1 in 1,000 people)

- Fainting on standing up

Side effects of unknown frequency (frequency cannot be estimated from the available data)

- Flushing
- Unstable angina (chest pain)
- High blood pressure on stopping treatment
- Methaemoglobinaemia (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 the Yellow Card Scheme Website at www.mhra.gov.uk/yellowcard

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

3. HOW TO STORE RECTOGESIC

- Keep out of the sight and reach of children.
- Do not use Rectogesic after the expiry date which is stated on the label and carton after ‘Exp.’ The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not freeze.
- Keep the tube tightly closed; use within 8 weeks of opening.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
- If your medicine become discoloured or show signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

4. CONTENTS OF THE PACK AND OTHER INFORMATION

What Rectogesic contains

One gram of rectal ointment contains 4 mg of glyceryl trinitrate (GTN). The recommended dose of 375 mg of this formulation contains approximately 1.5 mg GTN.

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.

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