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.

1. WHAT IS Rectogesic 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 pain 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 any of the other ingredients in the product (listed in section 6)
- if you are allergic to glyceryl trinitrate or to similar medicines
- if you have liver or kidney disease
- if you are taking 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),isosorbide dinitrate, amyl or butyl nitrite; medicines for high blood pressure or depression (tricyclic anti-depressants), acetylcysteine or alteplase

Take special care with Rectogesic:
- if you are allergic to 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 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, do not use 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.

Children and adolescents
Rectogesic is not recommended 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.

- Medicines that may increase the effect of Rectogesic on blood flow
- Medicines that may increase the effect of Rectogesic on 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)
- Commonly used tranquillizers
- 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
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (certain types of painkillers)
- 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)

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

Pregnancy and 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 effects of Rectogesic on blood pressure have been performed with Rectogesic.

- 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 (wax 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

- Paraffin.
- 375 mg of this formulation contains approximately 1.5 mg GTN.

3. HOW TO USE RECTOGESIC

3.1 Method of Administration

- Rectogesic is for Rectal Use.
- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is approximately 375 mg of ointment (approximately 1.5 mg glyceryl trinitrate) applied to the anal canal every 12 hours.
- 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 from your local store. The covered finger is placed alongside the 2.5 cm dosing line, which is provided on the outside carton, and a strip of ointment the length of the line is expressed onto the end of finger by gently squeezing the tube. Gently insert the ointment into the anal canal using the finger. The finger with the ointment must be inserted to the first finger joint (approximately 1 cm) into the anus.
- Apply the ointment every twelve hours as directed by your doctor and do not exceed the dose.
- Wash hands after use and dispose of the finger cot or plastic wrap (not down the toilet).
- Treatment may be continued until the pain goes away, or for up to a maximum 8 weeks. If your anal pain does not get better after using Rectogesic you should talk to your doctor again to check that something else is not causing the pain.
- If you use more Rectogesic than you should
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

4.1 Like all medicines, this medicine can cause side effects, although not everybody gets them.
- Serious side effects:
  - Anaphylactic reaction (allergic reaction, potentially fatal with face, lip, tongue or throat swelling, difficulty breathing, shortness of breath or collapse).
  - Rectal bleeding, rectal disorder
  - Methaemoglobinæmia (symptoms are blue/purple colouration of the skin and shortness of breath)

- Other known side effects associated with glyceryl trinitrate products (frequency unknown)
  - Flushing
  - High blood pressure on stopping treatment
  - Methaemoglobinæmia (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.

5. HOW TO STORE RECTOGESIC

5.1 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.
- Do not store below 0°C.
- 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

6.1 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.
- PL: 15814/1247
- POM

Manufactured by PHARBIL Waltrop GmbH, Waltrop, Germany.
- Procured from within the EU and repackaged by the Product Licence holder:
  - O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.
- Leaflet revision and issue date (Ref.): 05.02.2016.
- Rectogesic is a registered trademark of Strakan International Limited.
- To request a copy of this leaflet in Braille, large print or audio please call 01923 332 796.