PACKAGE LEAFLET: INFORMATION FOR THE USER

Rectogesic® 4 mg/g Rectal Ointment
Glyceryl trinitrate

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 in this leaflet:

1. What Rectogesic is and what 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 low blood pressure
- 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 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 treatment. 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 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 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.

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.

The following medicines may increase the blood pressure lowering effect of Rectogesic
- Medicines for depression (tricyclic anti-depressants)
- Medicines for erectile dysfunction (male impotence) (sildenafil citrate, tadalafil, vardenafil)
- Medicines for high blood pressure
- Diuretics ("water tablets")
- Commonly used tranquillizers
- 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.

3. HOW TO USE RECTOGESIC

Method of Administration
Rectogesic 4 mg/g Rectal Ointment 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 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 and seek medical attention immediately.**
- Allergic skin reactions (potentially severe). **If you have an allergic skin reaction stop using the ointment and seek medical attention.**

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.

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

Uncommon (may affect up to 1 in 100 people)
- Diarrhoea
- 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)
- Faintness on standing up

Side effects of unknown frequency (frequency cannot be estimated from the available data)
- Light-headedness, fainting
- Low blood pressure
- Irritation, rash or pain at area of application

Other known side effects associated with glyceryl trinitrate products (frequency unknown)
- 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:

HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. HOW TO STORE RECTOGESIC

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube 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

Once opened use up the ointment within 8 weeks.

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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Grünenthal Pharma Ltd
4045 Kingswood Road
Citywest Business Park
Citywest
Co. Dublin
Ireland

Manufacturer
PHARBIL Waltrop GmbH
Im Wirrigen 25
45731 Waltrop
Germany

This leaflet was last revised: August 2024