

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed with
a doctor's prescription only.

RECTOGESIC®

Rectal Ointment

Each 1 gram contains 0.4% glyceryl trinitrate.

Inactive and allergenic ingredients in the medicine - see section 6 in the leaflet.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

The medicine is not intended for children and adolescents under the age of 18, since studies have not been performed in this population.

1. WHAT IS THE MEDICINE INTENDED FOR?

To relieve pain caused by chronic anal fissures. An anal fissure is a tear in the skin lining the anal canal. Topical application of glyceryl trinitrate reduces the anal pressure and increases the blood flow, thereby reducing pain.

Therapeutic group: Organic nitrates.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or any of the additional ingredients contained in the medicine (see section 6 for the list of inactive ingredients), or to similar medicines.
- you are pregnant or breastfeeding.
- you suffer from low blood pressure.
- you suffer from blood vessel or heart disorders.
- you suffer from closed-angle glaucoma – a condition where pressure inside the eye rises rapidly, causing loss of vision.
- you suffer from migraines or recurrent headaches.
- you suffer from increased intracranial pressure or high pressure within the skull (such as: head injury or cerebral hemorrhage - bleeding from a ruptured blood vessel in the brain that can be fatal without prompt medical treatment, cerebral hemorrhage [a type of stroke] or abnormal cerebral circulation [inadequate amount of blood reaches the brain]).
- you suffer from anemia (low iron level in your blood).
- you are taking: medicines for erectile dysfunction, such as: sildenafil, tadalafil, vardenafil; medicines for angina pectoris or heart pain, such as: glyceryl trinitrate (GTN), isosorbide dinitrate, amyl or butyl nitrite; antihypertensives or medicines for depression (tricyclic antidepressants); acetylcysteine or alteplase.

Special warnings regarding use of the medicine

- Consult the doctor before starting treatment if you suffer, or have suffered in the past, from liver or kidney problems.
- Consult the doctor if you are being treated with heparin. The concentration of heparin in your blood needs to be closely monitored, as it may be necessary to alter its dosage. In this case, refer to the doctor before discontinuing use of Rectogesic.
- If you also have hemorrhoids and notice more bleeding than usual, stop using Rectogesic and discuss this with the doctor.
- Refer to the doctor if you suffer from severe headaches when using Rectogesic. The doctor will decide if it is necessary to change the dosage of Rectogesic or if treatment should be discontinued.
- Rectogesic may cause a drop in blood pressure. Therefore, get up slowly when transitioning from a lying/sitting position to a standing position, otherwise you might feel faint.
- If you are sensitive to any food or medicine, inform the doctor before using the medicine.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Medicines that may increase the blood pressure lowering effect of Rectogesic:
- Medicines for depression (tricyclic antidepressants) – **do not use together with Rectogesic.**
- Medicines for erectile dysfunction: sildenafil, tadalafil, vardenafil – **do not use together with Rectogesic.**
- Antihypertensives – **do not use together with Rectogesic.**
- Diuretics.
- Tranquillizers.
- Medicines to treat heart problems (isosorbide dinitrate, amyl or butyl nitrite) – **do not use together with Rectogesic.**

Additional medicines:

- Acetylcysteine may increase the effect of Rectogesic on blood flow – **do not use together with Rectogesic.**
- The effect of heparin (used to control blood clotting) may be decreased when used with Rectogesic.
- Alteplase (used to treat certain heart problems) – **do not use together with Rectogesic.**
- Taking Rectogesic with dihydroergotamine (to treat migraine) may increase the effect 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 (NSAIDs); certain types of painkillers might alter the therapeutic effect of Rectogesic.

❗ Use of the medicine and alcohol consumption

Exercise caution with alcohol consumption during the course of treatment, since the ointment may have a greater effect than usual and may even cause a drop in blood pressure.

❗ Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding.

❗ Driving and using machines

No studies on the effect of the medicine on ability to drive or operate machines have been performed. If you feel dizzy, sleepy or have blurred vision when starting to use the medicine, do not drive or operate machines until these effects pass.

❗ Important information about some of the ingredients in the medicine

This medicine contains lanolin, which may cause skin reactions (such as contact dermatitis). The medicine also contains propylene glycol, which may cause skin irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Consult with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only. The recommended dose is 375 mg of ointment (approximately 1.5 mg glyceryl trinitrate), inserted into the anal canal every 12 hours.

Do not exceed the recommended dose.

Use this medicine at set intervals, as determined by the attending doctor.

Do not swallow! This medicine is intended for external use only.

Instructions for use:

There is a possibility to insert the ointment, while the finger is covered with a finger cot that can be obtained in a pharmacy.

Place the covered finger alongside the 2.5 cm dosing line, marked on the outside carton.

Gently squeeze the tube to express a dose of ointment, at a length of the 2.5 cm dosing line, onto the finger.

Gently insert the finger with the ointment into the anus, to a depth of up to the first finger joint (approximately 1 cm).

Use the ointment every 12 hours, according to the doctor's instructions. **Do not exceed the recommended dose.** Wash your hands after the treatment. After use, close the tube with the cap.

Treatment duration: Continue treatment until the pain goes away, or for up to a maximum 8 weeks. If the pain does not get better after treatment with Rectogesic, consult the doctor.

If you accidentally took a higher dosage

If you used more ointment than required, you may feel dizzy. You may have palpitations or fast heart beats. If you experience these effects, wipe off the extra ointment and refer to a doctor or pharmacist immediately.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult the doctor. Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist. **Do not take medicines in the dark!** Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rectogesic may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects

Discontinue use and refer to a doctor immediately in the event of the following effects:

- Anaphylactic reactions (life-threatening allergic reactions, manifested by face, lip, tongue or throat swelling, difficulty breathing, shortness of breath or collapse).

Discontinue use and refer to a doctor in the following circumstances:

- Allergic skin effects (which may be severe).

Additional side effects

Very common side effects:

- Headache, which may be severe. If you develop a headache, wipe off the remaining ointment. If the headache is bothersome, consult the doctor about discontinuing use of the medicine.

Common side effects:

- Dizziness, nausea.

Uncommon side effects:

- Diarrhea, vomiting, rectal bleeding, rectal problems, anal discomfort, itching or burning of the anal canal, fast heart beat or palpitations.

Rare side effects:

- Weakness/faintness upon standing up.

Side effects of unknown frequency:

- Light-headedness, fainting.
- Low blood pressure.
- Irritation, rash or pain in the treated area.

Additional side effects (frequency unknown):

- Hot flushes.
- Chest pain (angina pectoris).
- High blood pressure after stopping the treatment.
- Methemoglobinemia (reduced oxygen level in the blood), manifested by shortness of breath and blue coloration of the skin.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffect_Medic@moh.gov.il

In addition, you can report to Perrigo via the following address:

www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in the original package, below 25°C. **Do not freeze.** Be sure to tightly close the tube after use.
- Use within 8 weeks of first opening.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Propylene glycol, white soft paraffin, anhydrous lanolin, hard paraffin, sorbitan sesquioleate.
- What the medicine looks like and the contents of the package: an aluminum tube containing 30 grams of off-white ointment.
- Registration Holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer: PHARBIL Waltrop GmbH, Waltrop, Germany.
- This leaflet was checked and approved by the Ministry of Health in May 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14066.31709