

## PACKAGE LEAFLET

### Package leaflet: Information for the patient

#### Procto-Glyvenol, 400 mg + 40 mg, suppositories

tribenoside + lidocaine

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **What is in this leaflet**

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

#### **1. What Procto-Glyvenol is and what it is used for**

Procto-Glyvenol suppositories is a medicinal product intended for local treatment of external and internal hemorrhoids.

Tribenoside has anti-inflammatory, antiedema, analgesic, anti-itching effect, as well as prevents damage to the vascular endothelial.

Lidocaine is a topical anesthetic substance and relieves discomfort caused by hemorrhoids, i.e. itching, burning, pain.

Procto-Glyvenol suppositories exerts a local action, practically does not have systemic effects.

#### **2. What you need to know before you use Procto-Glyvenol**

##### **Do not use Procto-Glyvenol:**

- if you are allergic to tribenoside or lidocaine or any of the other ingredients of this medicine (listed in section 6) or to other local anesthetics of amide structure.

##### **Warnings and precautions**

If you suffer from hepatic impairment talk to your doctor before using Procto-Glyvenol suppositories.

Procto-Glyvenol suppositories should be used with precaution in patients suffering from severe hepatic damage.

In addition to the treatment of hemorrhoids with Procto-Glyvenol, it is advisable to maintain proper hygiene of the anal area, to use of appropriate physical exercises and to have a proper diet in order to ensure adequate soft stool consistency.

Do not use this medicine orally.

Contact with the eyes should be avoided.

### **Children**

Do not use the medicinal product in children because there are no data on safety in this age group.

### **Other medicines and Procto-Glyvenol**

There has been no interaction with other medicines.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including those obtained without a prescription.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Procto-Glyvenol suppositories should not be used during the first 3 months of pregnancy. Procto-Glyvenol suppositories may be used as from the 4th month of pregnancy and during breast-feeding, however the recommended dosing should not be exceeded.

### **Driving and using machines**

Procto-Glyvenol suppositories has no or negligible influence on the ability to drive and use machines.

## **3. How to use Procto-Glyvenol**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Rectal administration.

One suppository should be applied in the morning and one suppository in the evening until acute symptoms have diminished, after which the dosage can be reduced to one suppository once a day.

Do not exceed the recommended doses.

Wash your hands thoroughly after each application.

### **Use in children**

Do not use the medicinal product in children because there are no data on safety in this age group.

### **How long should Procto-Glyvenol be taken**

Procto-Glyvenol suppositories should be taken until the symptoms are resolved.

Patients are advised to contact their doctor if there is no improvement after one week of application or if any other symptoms, which were not previously observed, are experienced, in order to exclude other potential causes of these disorders.

### **If you use more Procto-Glyvenol than you should**

There is no experience of overdosage with Procto-Glyvenol suppositories. Lack of a specific antidote for lidocaine.

Overdoses should not occur if the product is used according to the dosage schedule.

In case of an overdose, contact your doctor immediately.

**If you forget to use Procto-Glyvenol**

Do not take a double dose to make up for a forgotten dose.

**If you stop using Procto-Glyvenol**

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.

For the assessment of side effects, the following descriptions of frequency have been used:

|             |   |
|-------------|---|
| Very common | affects more than 1 user in 10                        |
| Common      | affects 1 to 10 users in 100                          |
| Uncommon    | affects 1 to 10 users in 1,000                        |
| Rare        | affects 1 to 10 users in 10,000                       |
| Very rare   | affects less than 1 user in 10,000                    |
| Not known   | frequency cannot be estimated from the available data |

**Rare side effects** (more than 1 person in every 10,000 treated but fewer than 1 person in every 1,000 treated):

- urticaria
- application site pruritus, application site rash, application site pain

**Very rare side effects** (may affect up to 1 in 10,000 people):

- Anaphylactic reaction
- Cardiovascular disorder
- Bronchospasm
- Angioedema
- Face edema

**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 Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Tel.: + 48 22 49 21 301, Faks: + 48 22 49 21 309, strona internetowa: <https://smz.ezdrowie.gov.pl>. By reporting side effects you can help provide more information on the safety of this medicine. Adverse reactions can also be reported to Marketing Authorisation Holder.

**5. How to store Procto-Glyvenol**

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

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Procto-Glyvenol contains**

- The active substances are tribenoside and lidocaine. 1 suppository contains 400 mg of tribenoside and 40 mg of lidocaine.
- The other excipients are: Fat (Witepsol E85), Fat (Witepsol W35).

### **What Procto-Glyvenol looks like and contents of the pack**

Procto-Glyvenol is yellowish-white suppository, conical in shape, uniform, without cracks, slightly fat, not soft.

Available package: 10 suppositories in Aluminium blisters, in a cardboard box.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Recordati Ireland Ltd.  
Raheens East  
Ringaskiddy, Co. Cork  
Ireland

### **Manufacturer**

Delpharm Huningue S.A.S.  
Site Industrial d'Huningue  
26 Rue de la Chapelle  
F-68333 Huningue  
France

Zeta Farmaceutici S.p.A.  
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**This leaflet was last revised in 02/2022**