

**Package Leaflet: Information for the Patient****Troxsal 20 mg/g gel**  
Troloxerutine**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine directed in this leaflet or as directed by your doctor, pharmacist or nurse.

- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- If you do not feel better or if you feel worse after 5 days, you must consult a doctor.

**What is in this leaflet**

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

**1. What Troxsal is and what it is used for**

Troxsal contains the active substance troloxerutin, which belongs to the class of medicines known as local vasoprotectors.

Troxsal is indicated for the symptomatic local treatment of:

- Chronic venous insufficiency;
- Varicose disease and hemorrhoids;
- Superficial thrombophlebitis, acute phlebitis and post-thrombophlebitic syndrome;
- Post-phlebosclerosis pain.

If you do not feel better or if you feel worse after 5 days, consult your doctor or pharmacist.

**2. What you need to know before you use Troxsal****Do not use Troxsal:**

- if you are allergic to troloxerutine, other flavonoids, or any of the other ingredients of this medicine (listed in section 6)

### **Warnings and precautions**

Înainte să utilizați Troxsal, adresați-vă medicului dumneavoastră, farmacistului sau asistentei medicale.

- do not apply Troxsal to mucous membranes, especially the eyes;
- do not apply Troxsal to areas with lesions, eczema, or open skin wounds;
- if a skin rash appears after applying troxerutin, discontinue treatment immediately;
- the use of troxerutin in patients with hemorrhoids requires a careful proctological diagnosis beforehand to exclude conditions that need other therapeutic interventions.

In the case of a hemorrhoidal crisis, the use of troxerutin does not exclude specific treatment for other anal conditions. Treatment with troxerutin should be of short duration.

If the symptoms do not subside quickly, the therapeutic approach should be reconsidered.

### **Other medicines and Troxsal**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Troxsal is not known to interact with any other medicines.

### **Pregnancy, breast-feeding and fertility**

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 using this medicine.

There is no data on adverse effects on the health of the fetus or newborn during the use of the medication in pregnant women.

As a precaution, the use of Troxsal is not recommended during the first trimester of pregnancy and during breast-feeding.

### **Driving and using machines**

Troxsal is not known to affect your ability to drive or use machines.

### **Troxsal contains methyl p-hydroxybenzoate**

It may cause allergic reactions on the skin.

## **3. How to use Troxsal**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Troxsal is for external use on the skin only.

#### *Adults*

Troxsal is applied externally in a thin layer to the areas affected by varicose veins or hemorrhoids - skin and intact anal mucosa. Gently massage it in. Applications should be made twice a day, in the morning and evening, for 2-3 weeks.

If after 5 days of treatment you do not observe improvement or if symptoms worsen, you should see a doctor who will reassess the treatment.

If necessary, you can apply Troxsal under occlusive or elastic bandages (graduated compression stockings).

#### *Children and Adolescents*

Troxsal is not recommended for use in children and adolescents due to the lack of safety data for this age group.

**If you use more Troxsal than you should**

No cases of overdose have been observed to date. In the event of accidental ingestion of a quantity of gel, contact your doctor immediately or go to the nearest hospital emergency department.

**If you forget to use Troxsal**

If you forget to use Troxsal, use it as soon as you remember.

Do not use double the amount to make up for a missed application.

**If you stop using Troxsal**

Troxsal should be used only as needed. You can stop the treatment as soon as you feel better.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Adverse reactions are classified according to frequency using the following convention:

Very common:	affecting more than 1 in 10 patients
Common:	affecting fewer than 1 in 10 patients
Uncommon:	affecting fewer than 1 in 100 patients
Rare:	affecting fewer than 1 in 1,000 patients
Very rare:	affecting fewer than 1 in 10,000 patients
Frequency not know	cannot be estimated from the available data

Skin irritations or hypersensitivity reactions, such as erythema (redness of the skin), pruritus (itching), and transient rashes, have been reported rarely. These adverse reactions completely disappear once the treatment is discontinued.

**Reporting Adverse Reactions**

Tell your doctor or pharmacist if you experience any side effects.

This includes any adverse reactions not mentioned in this leaflet. You can also report adverse reactions directly through the national reporting system, details of which are published on the website of the National Agency for Medicines and Medical Devices of Romania <http://www.anm.ro/>. By reporting adverse reactions, you can help provide additional information on the safety of this medicine.

**5. How to store Troxsal**

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

Do not use this medicine after the expiration date stated on the box, marked as EXP. The expiration date refers to the last day of that month..

Store below 25°C, in the original packaging.

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

**6. Contents of the pack and other information****What Troxsal contains**

- The active substance is troxerutine. One gram of gel contains 20 mg of troxerutine.
- The other ingredients are: carbomer 980, triethanolamine, methyl p-hydroxybenzoate (E 218), disodium edetate, and purified water.

**What Troxsal looks like and contents of the pack**

Troxsal is presented as a homogeneous gel, yellow, transparent to slightly opalescent. It comes in a box

with an aluminum tube sealed with a membrane and closed with a plastic cap, containing 45 g of gel.

**Marketing authorisation holder and manufacturer**

S.C. Slavia Pharm S.R.L.  
B-dul Theodor Pallady nr. 44C  
Sector 3, cod 032266, Bucharest  
Romania

**This leaflet was last revised in January 2021.**

**Other Sources of Information**

Detailed information about this medicine is available on the website of the National Agency for Medicines and Medical Devices of Romania: <http://www.anm.ro/>.