

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

The medicine is dispensed without a doctor's prescription

Rectozorin® Ointment

Composition:

Bismuth oxychloride	8.0%
Thymol biiodide	2.0%
Zinc oxide	10.0%
Benzocaine	4.0%
Menthol	0.25%

Rectozorin® Suppositories

Each suppository contains:

Bismuth subgallate	100 mg
Thymol biiodide	150 mg
Tannic acid	20 mg
Zinc oxide	100 mg
Benzocaine	100 mg
Menthol	5 mg

For information on inactive and allergenic ingredients, see section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Further information”.

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

Use the medicine according to the instructions in the dosage section of this leaflet. Consult a pharmacist if you need more information. Refer to the doctor if the symptoms of the disease worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the relief of pain caused by hemorrhoids.

Therapeutic group

Preparations to treat hemorrhoids, for rectal use.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see section 6 – “Further information”).

Before treatment with Rectozorin tell the doctor if:

- You have a known sensitivity to any of the ingredients of the medicine.
- You are pregnant, or if you are breastfeeding.
- You suffer, or have suffered in the past, from impaired kidney or urinary system function.
- Your hemorrhoids are bleeding or if the skin is inflamed, damaged or injured at or near the treatment site.
- You are under 18 years of age.

Special warnings regarding use of the medicine

- Do not use this medicine frequently, or for a long period, without consulting a doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before taking the medicine.
- If you are sensitive to iodine, consult your doctor before using this medicine.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy, breastfeeding and fertility

Do not use the medicine without consulting a doctor before starting treatment if you are pregnant or breastfeeding.

Important information about some of the ingredients of the medicine

Rectozorin Ointment contains wool fat, which can cause a localized skin reaction (such as contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Recommended dosage unless otherwise instructed by your doctor:

Suppositories:

One suppository in the morning and in the evening, and following each bowel movement.

Ointment:

Apply the ointment to the rectal area in the morning and in the evening, and following each bowel movement.

Do not exceed the recommended dose.

If there is no improvement in your condition within a few days, refer to your doctor.

Directions for use

Do not swallow! This medicine is intended for use in the rectum only. **The medicine is not usually intended for children under 18 years of age.**

Ointment:

- Wash and dry the rectal area.
- Apply a small amount of the ointment and rub it in gently.
- Close the tube tightly.
- Wash your hands.

If, according to the doctor's instructions, the ointment should be inserted into the rectum, proceed as follows:

- Attach the applicator to the open end of the tube.
- Insert the applicator tip into the rectum.

- Gently squeeze the tube to deliver the ointment.
- When finished, separate the applicator from the tube and wash it thoroughly with warm water and soap.
- Close the tube tightly.

Suppositories:

- Opening instructions: Separate one suppository from the suppository strip. To remove the plastic wrapper, separate the tabs on the flat part of the plastic wrapper and pull to the sides until the suppository comes out. The suppository may be moistened with a little water to ease its insertion.
- Lie down on your side and insert the suppository deep into the rectum using your finger.
- When you finish, wash your hands thoroughly.

Note: If the suppository is too soft, it may be chilled in a refrigerator for about 30 minutes or cooled under cold water before removing the plastic wrapper.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without an explicit instruction from a doctor!

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, use of Rectozorin 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.

Severe side effects (rare):

Discontinue use of Rectozorin and refer to a doctor immediately if:

- You have bleeding in the anal area.
- You have local irritation, rash or inflammation (which did not exist before using the preparation).

Additional side effects:

- Increased bowel movement.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the 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://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store these medicines below 25°C.**
- Rectozorin Ointment can be used for up to 12 months after first opening of the tube.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Ointment: petrolatum, mineral oil, wool fat, purified water, yellow wax, cholesterol

Suppositories: witepsol E-76, witepsol W-35

What the medicine looks like and the contents of the package:

Ointment: A light yellow ointment.

The package contains an aluminum tube containing 50 grams of ointment.

Suppositories: The suppositories are yellowish to light brown.

The package contains 12 suppositories.

Name of Manufacturer and License Holder and its Address: Teva Pharmaceutical Industries Ltd., P.O. Box 3190, Petah-Tikva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Rectozorin Ointment:

135.34.20466.00/01

Rectozorin Suppositories:

030.68.20618.00

The leaflet was revised in January 2021 according to MOH guidelines.