

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

The medicine is dispensed without a doctor's prescription

Rectozorin[®] Ointment

Composition

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

Rectozorin[®] Suppositories

Composition

Each suppository contains:

Thymol biiodide	150 mg
Bismuth subgallate	100 mg
Zinc oxide	100 mg
Benzocaine	100 mg
Tannic acid	20 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 section 3 of this leaflet. Consult a pharmacist if you need further information. Refer to the doctor if the symptoms of the disease worsen or do not improve. The medicine is not intended for patients under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Relief of hemorrhoid pain.

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".
- You are sensitive to local anaesthetics (procaine, butacaine) or para-aminobenzoic acid, parabens or paraphenylenediamine (PPD) or to hair dyes. See section 6 – "Further information".
- These are large areas of skin, skin rash, sunburns, damaged or inflamed skin or in the mouth or eyes.
- You have a slow or irregular heart rate.
- You have a history or suspicion of abnormal pigment levels in the blood.
- There is a combination with sulfonamides or cholinesterase inhibitors.

Special warnings regarding use of the medicine

Before treatment with Rectozorin tell the doctor if:

- You are pregnant, or if you are breastfeeding.
- You have rectal bleeding, bloody stool or if you are concerned that the hemorrhoids you are experiencing are not the source of your bleeding.
- You have generalized itching throughout the body.
- You are under 18 years of age.
- You are sensitive to any food or medicine.
- You are sensitive to iodine.

Do not use this medicine frequently or for a prolonged period without consulting a doctor.

Children and adolescents

The medicine is not intended for patients under 18 years of age.

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

If you are pregnant or breastfeeding, do not use the medicine without consulting a doctor before starting treatment.

Driving and operating machinery

Rectozorin Ointment and Suppositories have no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine

Rectozorin Ointment contains lanolin (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 the doctor:

Suppositories:

One suppository in the morning and in the evening, as well as after each bowel movement.

Ointment:

Apply the ointment to the rectal area in the morning and in the evening, as well as after each bowel movement.

Do not exceed the recommended dose.

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

Directions for use

Do not swallow! This medicine is intended for use in the rectum only.

The medicines are not intended for use under 18 years of age.

Ointment:

- Gently 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.
- Gently insert the applicator tip into the rectum.
- Gently squeeze the tube to eject the ointment.
- When finished, separate the applicator from the tube and wash it thoroughly with hot water and soap.
- Close the tube tightly and wash your hands.

Suppositories:

- Gently wash and dry the rectal area.
- 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 sideways until the suppository comes out. The suppository may be moistened with a little water to ease its insertion (see note below).
- Lie down on your side and insert the suppository deep into the rectum using your finger.
- When finished, 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 has 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 unless explicitly instructed to do so by the doctor!

If you forgot to take the medicine, take the next dose as necessary. Do not take a double dose to compensate for the forgotten dose.

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.

Rare side effects (effects that occur in up to 1 user in 1,000):

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

- You have a hypersensitivity reaction, which can be manifested by a rash, redness of the skin, minor swelling of the skin, blisters, worsening itching and/or irritation.

Additional side effects whose frequency is unknown (effects whose frequency have not yet been determined):

- Burning, redness, irritation, itching or pain when applying/inserting the medicine. If these effects persist for more than a few days, consult a doctor.

If a side effect occurs, if one of the side effects worsens or if you are suffering 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 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 these medicines below 25°C.
- Rectozorin Ointment can be used for up to 12 months after first opening the tube, but no later than the expiry date that appears on the package.
- Do not throw medicines into the wastewater or household waste. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

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 yellowish ointment.

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

Suppositories:

The suppositories are yellowish to light brown.

The package contains 12 suppositories.

Name of Manufacturer and License Holder and its Address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

The patient leaflet was revised in November 2022 according to MOH guidelines.

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

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