Summary of Product Characteristics

Rectozorin Suppositories
Rectozorin Ointment

1. Name of the medicinal product

Rectozorin Suppositories
Rectozorin Ointment

2. Qualitative and quantitative 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

Ointment:

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

Excipient with known effect:
Rectozorin Ointment contains wool fat (lanolin). Wool fat may cause local skin reactions (e.g. contact dermatitis).
For full list of excipients, see section 6.1

3. Pharmaceutical form

Rectozorin suppositories- Yellowish to light brown suppositories.
Rectozorin ointment- Light yellow homogeneous ointment.

4. Clinical particulars

4.1 Therapeutic indications

.**Suppositories:** Symptomatic relief of pain and discomfort in hemorrhoids.

Ointment: Symptomatic relief of pain and discomfort in irritated anorectal tissues in: hemorrhoids, proctitis, papillitis, cryptitis, fissures and following anorectal surgery.

4.2 Posology and method of administration

Suppositories: Anal insertion.

Ointment: Topical.

For short term use only. If pain persists for more than few days, or worsens, seek medical advice.

Suppository:

Dosage

one suppository in the morning, one suppository in the evening and after every time you empty your bowels.

Direction for use

- Wash your hands with soap and water. Dry your hands with a clean towel or a paper towel.
- Remove any wrapping from the suppository.
- If necessary, you can wet the suppository to make it easier to insert the suppository.
- If the suppository is too soft, you can cool it in the refrigerator for 30 minutes.
- Lie down on your side and insert the suppository into the rectum, push the suppository with your finger.
- Wash your hands with soap and water.

Ointment:

Dosage

Apply the ointment once in the morning, once in the evening and after every time you empty your bowels.

Direction for use

- Wash your hands with soap and water. Dry your hands with a clean towel or a paper towel.
- Apply a small amount of medicine to the sore area.
- Wash your hands with soap and water

For inserting the ointment inside the rectum:

- Remove the cap from the tube
- Attach the applicator to the tube
- Squeeze gently the ointment inside the rectum
- When you finish, remove the applicator from the tube
- Wash the applicator with soap and warm water
- Close the tube

Children under 18 years old

Not recommended.

4.3 Contraindications

-Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 . Hypersensitivity to paraaminobenzoic acid (PABA), parabens or paraphenylenediamine or to commercial hair dyes as there is cross-sensitivity between these products and benzocaine.

-A history of allergy to local anesthetics such as procaine, butacaine or any other 'caine' anesthetics.

-In patients who have a history of or are suspected to have methaemoglobinaemia (see section 4.8).

-Do not use with sulphonamides (see section 4.5).

-Do not use with cholinesterase inhibitors (see section 4.5).

-Do not apply the ointment to large areas of skin, eczematous, sunburnt, infected or broken skin.

4.4 Special warnings and precautions for use

-Patients with rectal bleeding or blood in the stool should talk to their doctor before using this product as these conditions may be the symptom of a more serious underlying disorder.

-Local anesthetics should not be used in patients with complete heart block.

-Not for use on extensive body area or on the mouth or eyes or under conditions in which significant inhalation is likely.

-If symptoms persist or worsen, patients should be instructed to stop use and consult a physician.

4.5 Interaction with other medicinal products and other forms of interaction

Sulphonamides: Benzocaine is metabolized to para-aminobenzoic acid and may antagonize the effects of sulphonamides.

Cholinesterase Inhibitors: Cholinesterase inhibitors inhibit the metabolism of benzocaine.

4.6 Fertility, pregnancy and lactation

Pregnancy

This product should not be used during pregnancy and lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing fetus or nursing infant.

Do not use in pregnancy without first consulting a doctor.

There are limited amounts of data from the use of benzocaine in pregnant women.

Breast feeding

There is insufficient information on the excretion of benzocaine metabolites in human milk.

Do not use during breast feeding without first consulting a doctor.

Fertility

No known effects

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during Post-Marketing experience with **Zinc Oxide** (topical use) and with benzocaine are included in the Table below. The frequencies are provided according to the following convention:

Very common ≥1/10

Common ≥1/100 and < 1/10

Uncommon ≥1/1,000 and <1/100

Rare ≥1/10,000 and <1/1,000

Very rare <1/10,000

Not known (cannot be estimated from the available data)

	System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Zinc oxide	**Immune System Disorders**	Rare	Hypersensitivity
Benzocaine		Not known	Hypersensitivity reactions, dermatitis allergic
Zinc oxide	**General Disorders and Administration site conditions**	Not known	Application site reactions (including Burn, erythema, Exfoliation, Irritation, Pain, Pruritus, Rash and Urticaria)
Benzocaine	**Blood and Lymphatic System Disorders**	Not known	Methaemoglobinaemia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

The ingestion of topical zinc oxide can potentiate gastrointestinal symptoms like stomach pain, nausea, vomiting, and diarrhoea.

Symptoms of acute oral overdose of bismuth-containing preparations may include nausea, vomiting, renal failure, and rarely liver damage. Encephalopathy and discoloration of mucous membranes may occur with chronic overdose.

Treatment of a large acute overdose should include gastric lavage, purgation with magnesium sulphate and complete bed rest. If necessary, give oxygen and general supportive measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other agents for treatment of haemorrhoids and anal fissures for topical use*, ATC code:* C05AX

Rectozorin Suppositories provide antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions.

Rectozorin ointment provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions. It also provides lubricating properties for use with suppositories.

Bismuth Oxide, Zinc Oxide and Bismuth Subgallate exert a protective action on mucous membranes and raw surfaces. They are mildly astringent and are reported to have antiseptic properties.

Zinc oxide is an astringent and mild antiseptic and probably owes its actions to the ability of the zinc ion to precipitate protein, but other mechanisms may be involved. Zinc oxide is also used to absorb skin moisture and decrease friction and discourage growth of certain bacteria

Benzocaine applied to the skin acts as a topical local anesthetic, acting on nerve endings and receptors, temporarily reducing the itching and minor pain associated with various thermal, mechanical or chemical stimuli. The base also helps soothe, lubricate, and protect irritated skin.

5.2 Pharmacokinetic properties

When used as directed, some benzocaine applied topically may be absorbed through the skin and mucous membranes and is hydrolyzed by esterases in the plasma and in the liver, but this should be of negligible consequence. Benzocaine has the quickest onset and shortest duration of action of the commonly used topical anesthetics.

5.3 Preclinical safety data

The active ingredients of Rectozorin are well known constituents of medicinal products, and their safety profile is well documented.

6. Pharmaceutical particulars

6.1 List of excipients

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

Rectozorin suppositories: witepsol E-76, witepsol W-35

6.2 Incompatibilities

None known.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store at a temperature below 25°C.

6.5 Nature and contents of container

Suppositories- blister of 12 suppositories. .

Ointment- Aluminum tube containing 50 gr.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. LICENCE HOLDER AND MANUFACTURER

Teva Israel Ltd, Israel

8. REGISTRATION NUMBER(S)

Rectozorin Supp: 030-68-20618

Rectozorin ointment: 135-34-20466

This leaflet was revised in June 2023 according to MOHs guidelines.