

# 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

## **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.

- Do not use in patients who have a history of, or are suspected to have methaemoglobinaemia (see section 4.8). The risk of methaemoglobinaemia is increased in patients who have a reduced haematological capacity for oxygen transport including those with glucose-6-phosphate dehydrogenase (G6PD) deficiency, haemoglobinopathies, or anaemia.

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

-Do not use with cholinesterase inhibitors or in patients with reduced cholinesterase activity (see section 4.5).

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

-Do not use with occlusive dressings.

## **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 no or 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. A risk to new-borns/infants cannot be excluded.

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  $\geq 1/10$

Common  $\geq 1/100$  and  $< 1/10$

Uncommon  $\geq 1/1,000$  and  $< 1/100$

Rare  $\geq 1/10,000$  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	Rare	Hypersensitivity

	<b>Disorders</b>		
<b>Benzocaine</b>		Not known	Hypersensitivity reactions
<b>Zinc oxide</b>	<b>General Disorders and Administration site conditions</b>	Not known	Application site reactions (including Burn, erythema, Exfoliation, Irritation, Pain, Pruritus, Rash and Urticaria)
<b>Benzocaine</b>	<b>Blood and Lymphatic System Disorders</b>	Not known	Methaemoglobinaemia
<b>Benzocaine</b>	<b>Skin and Subcutaneous Tissue Disorders</b>	Not known	Dermatitis allergic

### **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.

The systemic toxicity of local anaesthetics such as benzocaine mainly involves the CNS and the cardiovascular system. Overdose may be associated with symptoms of methaemoglobinaemia which in mild cases may be asymptomatic or be associated with mild cyanosis. Symptoms of acute methaemoglobinaemia may include dyspnoea, headache, malaise, giddiness, and altered mental state. It is more likely when benzocaine is used on large areas of skin, on broken skin or when used with occlusive dressings.

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.

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.

### **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.,

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

## **8. REGISTRATION NUMBER(S)**

Rectozorin Supp: 030-68-20618

Rectozorin ointment: 135-34-20466

**Revised in November 2025.**