

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

The medicine is dispensed without a doctor's prescription

**Baby Gum  
Gel**

**Active ingredients:**

Choline salicylate 8.7% w/w

Cetalkonium chloride 0.01% w/w

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

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

Use the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information. If the symptoms worsen or do not improve after 3 days, refer to a doctor.

**1. What is the medicine intended for?**

Antiseptic and pain-relieving gel for the mouth cavity.

The medicine is intended for the relief of teething pains, mouth ulcers, denture irritation and cold sores.

**Therapeutic group:**

Choline salicylate – pain reliever

Cetalkonium chloride - antiseptic

**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 the medicine contains (for the list of the additional ingredients, see section 6).
- You are sensitive (allergic) to salicylates, aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or to cetylpyrдинium.
- You are taking aspirin or other salicylates (unless instructed so by the doctor).
- Do not use in infants under the age of 4 months.
- You suffer from an active stomach ulcer, or if you have a history of recurrent stomach ulcers.
- Do not use in cases of viral illnesses, such as influenza or chickenpox, particularly in children and adolescents under 16 years of age for fear of Reye's syndrome.

**Special warnings regarding the use of the medicine**

- If there is no improvement after 3 days, consult the doctor.
- Do not use this medicine frequently or for a prolonged period without consulting the doctor.
- Make sure to follow the instructions for use. Do not exceed the recommended dose and the frequency of use, particularly in babies and children under 16 years of age, since too frequent use or too high a dose may cause salicylate poisoning. See 'If you accidentally took a higher dosage' section.
- Avoid contact of the gel with the eyes.

**Children and adolescents:**

Do not use in infants under the age of 4 months.

**Drug interactions:**

**If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially if you are taking:**

- Aspirin and other salicylates: do not use concurrently with Baby Gum, unless instructed by the doctor.
- Anticoagulants: use of Baby Gum concurrently with these medicines may enhance their effect.
- Anti-gout medicines (e.g. probenec acid): use of Baby Gum concurrently with these medicines may reduce their effect.

#### **Use of the medicine and food**

Do not eat or drink close to application in the mouth.

#### **Pregnancy and breastfeeding:**

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

- Salicylates may prolong bleeding and cause bleeding in the newborn or the mother, and therefore do not use them in advanced stages of pregnancy.
- Salicylates are excreted in small amounts into breastmilk, and in very rare cases may cause side effects in the baby.

#### **Important information about some of the medicine's ingredients:**

- Every tube contains approximately 4 grams (47% v/v) ethanol (alcohol).
- Every dose of approximately 0.5 cm contains a small amount of alcohol (about 70 mg) which is equivalent to less than 2 milliliters beer or 1 milliliter wine. This amount of alcohol does not have any noticeable effects. May cause a burning sensation on damaged skin/mucous.
- This medicine contains less than 1 mmol sodium (23 mg) in each dose, i.e. it is considered 'sodium-free'.
- The gel contains sodium metabisulfite which in rare cases may cause severe hypersensitivity reactions and bronchospasm.

### **3. How to use the medicine?**

Check with the doctor or pharmacist if you are not certain about the dosage and manner of treatment with the medicine.

Apply to the sore area in the mouth cavity.

Do not swallow.

#### **The standard dosage is usually:**

**Children from 4 months until 16 years of age:** put about 0.5 centimeter (pea size) gel on a clean finger and massage into the sore area. This treatment may be repeated every 3 to 4 hours, but not more than 6 times in 24 hours.

**Adults:** put 1-1.5 centimeters of gel on a clean finger and massage into the sore area. This treatment may be repeated every 3 to 4 hours, but not more than 6 times in 24 hours.

#### **Do not exceed the recommended dose.**

If there is no improvement within 3 days or if there is any deterioration, refer to the doctor.

#### **If you accidentally took a higher dosage**

If a higher dosage was used, refer immediately to a doctor or a hospital emergency room and bring the medicine package with you. Symptoms of a salicylate poisoning-related overdose include: nausea, vomiting, fever, confusion and disorientation, ringing in the ears, hyperventilation, dehydration, dizziness, bleeding from the digestive system, acid/base balance disturbances, convulsions, coma.

#### **If you forgot to take the medicine**

If necessary - use the gel according to the instructions in this section. Do not use a double dose to compensate for the forgotten dose.

Do not use or 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 concerning the use of the medicine, consult the doctor or pharmacist.

#### **4. Side effects**

As with any medicine, the use of Baby Gum 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.

**Stop treatment and refer to a doctor immediately if** an allergic reaction develops such as an asthma attack, bronchospasm or breathing difficulties.

#### **Additional side effects**

*Side effects of unknown frequency (effects whose frequency has not yet been determined):* Inflammation, burning, numbness or stinging of the mouth and/or gums.

#### **Side effects and drug interactions in children and babies:**

Cases of a reaction suspected of being Reye's syndrome and/or salicylate poisoning in children who have applied medicines containing choline salicylate have been reported, but the causality was not established in these cases. See 'If you accidentally took a higher dosage' section.

**If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which leads 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, must be stored in a closed place out of the reach and sight of children and/or babies, 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.
- **Storage conditions:** store below 25°C. Make sure that the cap is closed tightly after each use. After the first opening of the tube, the gel may be used for 2 months, but no later than the expiry date imprinted on the package.

#### **6. Additional information**

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

Ethanol, choline salicylate, glycerin, hydroxypropyl methylcellulose 4000, sodium cyclamate, oil of anise, menthol, cetalkonium chloride, sodium metabisulfite, hydrochloric acid, purified water.

**What does the medicine look like and what does the package contain?**

Transparent gel in an aluminum tube. The tube contains 10 gram.

**Manufacturer and Registration Holder:** Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

**Marketed exclusively by:** Super-Pharm (Israel) Ltd., P.O. Box 2171, Herzliya 4672516

**Medicine registration number in the National Medicines Registry of the Ministry of Health: 131-49-31109**

Revised in November 2023 according to MOH's guidelines.