

Patient Leaflet According to the Pharmacists' Regulations (Preparations) -1986

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

Use this 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, consult your doctor.

1. What is the medicine intended for?

Antiseptic and pain relieving gel for the mouth.

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 a 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 4 months of age.
- You suffer from an active stomach ulcer, or you have a history of recurrent stomach ulcer.
- 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 this medicine:

- If there is no improvement after 3 days, consult your doctor.
- Do not use this medicine frequently or for a long period without consulting your doctor.
- Make sure to follow the instructions for use. Do not exceed the recommended dosage and the frequency of use, particularly in infants and children under 16 years of age, since too frequent use or too high a dosage 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 4 months of age.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your 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. probenic acid): use of Baby Gum concurrently with these medicines may reduce their effect.

Use of the medicine and food

Do not eat or drink in close proximity to the 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 breastfeeding.

- Salicylates may prolong bleeding and contribute to maternal or neonatal bleeding, therefore do not use in advanced stages of pregnancy.
- Salicylates are excreted in small amounts into breast milk, and in very rare cases may cause side effects in the infant.

Important information about some of the medicine's ingredients:

- Every tube contains approximately 4 grams (47% v/v) of ethanol (alcohol).
- Every dose of approximately 0.5 cm contains a small amount of alcohol (about 70 mg).
- The gel contains sodium metabisulfite which in rare cases may cause severe hypersensitivity reactions and bronchospasm.

3. How to use this 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 four months until 16 years of age: put about 0.5 cm (pea size) gel on a clean finger and massage into the sore area. The treatment may be repeated every 3 to 4 hours, but no more than 6 times in 24 hours.

Adults: put about 1-1.5 cm of gel on a clean finger and massage into the sore area. The treatment may be repeated every 3 to 4 hours, but no 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 your doctor.

If you accidentally took a higher dosage

If a higher dosage was used, go 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 your doctor or pharmacist.

4. Side effects

Like 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 your doctor immediately if an allergic reaction develops such as an asthma attack, bronchospasm or difficulties breathing.

Additional side effects

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

Side Effects and Drug Interactions in Children and Infants:

Cases have been reported of a reaction suspected of being Reye's syndrome and/or salicylate poisoning in children who have applied medicines containing choline salicylate, but the causality was not proven 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 your 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) 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 infants, 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 appear 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 within 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, glycerin, hydroxypropyl methylcellulose 4000, sodium cyclamate, oil of anise, menthol, 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 grams.

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: 1314931109

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