

## Summary of Product characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Baby Gum Gel

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active ingredients

Choline salicylate 8.7%  
Cetalkonium chloride 0.01%

#### **Excipient**

Ethanol 38% w/w

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Clear, colorless oromucosal gel.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

As an antiseptic and local pain reliever for mouth ulcers, teething pain, denture irritation, and cold sores.

#### 4.2 Posology and method of administration

By topical application to the oral mucosa.

Adults: Using a clean finger, massage approximately 1-1.5 cm of the gel onto the sore area, not more than once every 3-4 hours. Do not apply more than six doses in any 24 hour period.

Children (from four months to 16 years old): Using a clean finger, massage approximately 0.5 cm (a pea size amount) of gel onto the sore area, not more than once every 3-4 hours. Do not apply more than six doses in any 24 hour period. Not suitable for infants under four months.

Do not exceed the stated dose.

If symptoms do not improve after 3 days seek medical advice (see section 4.4).

Older people:

There is no indication that dosage need be modified in the elderly.

#### 4.3 Contraindications

Not to be used in infants under four months.

Hypersensitivity to choline salicylate, cetalkonium chloride or to any of the excipients in the product listed in section 6.1.

Not to be used in patients with hypersensitivity to salicylates, aspirin or other NSAIDs, to cetylpyrdinium or to any of the excipients.

Not to be used in patients with active or a history of recurrent peptic ulceration.

Do not use in patients currently suffering from viral illnesses such as varicella (chicken pox) or influenza infection particularly in children and adolescents under 16 years of age due to the risk of precipitating Reye's syndrome in this patient population.

#### **4.4 Special warnings and precautions for use**

The recommended dose and frequency should not be exceeded especially in children under 16 years due to risk of Reye's syndrome and salicylate poisoning (see section 4.8 & 4.9).

This product contains salicylate and should not be used with aspirin or other salicylates except under the direction of a doctor or dentist.

Each tube contains about 4 gram (38% w/w) ethanol (alcohol).

Each dose of about 0.5 cm contains a small amount of alcohol (about 70 mg). The amount in each dose of alcohol in this medicine is equivalent to less than 2ml beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects. It may cause burning sensation on damaged skin.

This medicine contains less than 1 mmol sodium (23mg) in each dose, that is to say essentially 'sodium-free'.

This product contains sodium metabisulfite which may rarely cause severe hypersensitivity reactions and bronchospasm.

Contact your doctor or dentist if you have an active or recurring stomach ulcer (see section 4.3).

Contact your doctor or dentist if you are currently suffering from a viral infection such as varicella (chicken pox) or influenza infection (see section 4.3.)

Consult your doctor if you are pregnant or breastfeeding.

If there is no improvement after 3 days or there is aggravation of the condition, the doctor or dentist should be consulted.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Salicylates may enhance the effect of anticoagulants and inhibit the action of uricosurics.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy:**

There is clinical evidence of the safety of salicylates in pregnancy, but they may prolong bleeding and contribute to maternal and neonatal bleeding, and are best avoided at term.

##### **Breast-feeding:**

Salicylates are excreted at low concentrations in breast milk, and may adversely affect the infant in very rare cases.

##### **Fertility:**

There is no information on the effects of topical oral choline salicylate and fertility.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with topical oral salicylates at OTC doses, in short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with salicylates are given below, listed by system organ class and frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $< 1/10$ ), uncommon ( $\geq 1/1000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1/1000$ ), very rare ( $< 1/10,000$ ); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

There have been post-marketing reports of cases of suspected Reyes syndrome and possible salicylate toxicity in children who had a history of use of choline salicylate gels but causality has not been established.

System Organ Class	Frequency	Adverse Events
Immune system disorders	Not known	Hypersensitivity
Nervous system disorders	Not known	Paraesthesia (transient numbing and stinging)
Respiratory, thoracic and mediastinal disorders	Not known	Bronchospasm and asthma <sup>1</sup>
Gastrointestinal disorders	Not known	Stomatitis

### Description of Selected Adverse Reactions

<sup>1</sup> Salicylates may precipitate bronchospasm and induce asthma attacks in susceptible patients. They can cause stomatitis, burns and allergic reactions.

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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

- i) Dealing with the potential for toxicity with local application, especially in infants:

As choline salicylate is absorbed across the buccal mucosa, the possibility exists for toxicity, especially in infants hence the need for caution not to exceed the stated dose and monitor for any signs of suggested salicylism.

Symptoms: Nausea, vomiting, tinnitus, hyperventilation, high fever, confusion, dehydration, disorientation, dizziness, coma and/or convulsions are common. Gastrointestinal haemorrhage is frequent. Some degree of acid-base disturbance is present in most cases.

- ii) Dealing with overdose in the event of accidental ingestion of product:

Serum salicylate levels above 3.6 mmol/l in adults (2.2 mmol/l in children) are likely to be toxic and levels of 5.4 mmol/l or above are fatal.

Treatment: Drug absorption can be stopped by induced vomiting or gastric lavage within an hour of ingestion. Activated charcoal is to be given by mouth if the patient is suspected of ingesting more than 120mg/kg of salicylate within 1 hour of presentation to enhance excretion.

The plasma salicylate concentration should be measured if ingestion of more than 12mg/kg of salicylate is suspected.

Elimination is increased by urinary alkalisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urinary pH should also be monitored.

Haemodialysis may be used for severe poisoning in patients with plasma salicylate concentrations >700mg/L or in patients with severe clinical or metabolic symptoms. Vulnerable patients such as children or the elderly may require dialysis at an earlier stage.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC code: N02BA03 / Salicylic acid and derivatives

Choline salicylate is the choline salt of salicylic acid and its pharmacology is essentially that of salicylic acid. It has exhibited anti-inflammatory analgesic and antipyretic actions in animal models, and is taken orally or is applied topically in man for the relief of pain and inflammation. Like salicylic acid, it has no antithrombotic activity and shows a low potential for production of gastrointestinal injury when given by the oral route. The pharmacological actions of choline salicylate are thought to be primarily mediated through inhibition of prostaglandin production, although effects on leukotriene pathways, kinin release and nerve conduction have been proposed.

Cetalkonium chloride is a quaternary ammonium antimicrobial agent, being bactericidal towards both gram positive and gram negative organisms, but with preference for the former.

### **5.2 Pharmacokinetic properties**

Choline salicylate is absorbed from the gut and is likely to be absorbed across mucous membranes such as all buccal mucosa. Metabolism of salicylic acid is by glycine and phenolic or acyl glucuronate conjugation with small amounts undergoing hydroxylation. The plasma half-life of salicylic acid is 2-4 hours. Both metabolites and a small amount of intact salicylic acid are excreted, mainly in the urine. Salicylic acid is highly (80-90%) protein bound and although it has a low apparent volume of distribution of around 0.151 l/kg it is widely distributed throughout extracellular water and most tissues.

### **5.3 Preclinical safety data**

No preclinical findings of relevance to the prescriber have been reported.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

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

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

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

#### **6.4 Special precautions for storage**

Store below 25°C.

After first opening of the tube, the gel may be used within 2 months, but no later than the expiry date marked on the package.

#### **6.5 Nature and contents of container**

10 g gel in an aluminium tube.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 REGISTRATION HOLDER**

Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301, Israel.

Registration number: 131-49-31109

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

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