Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bonjela Teething Gel Oromucosal GelCholine Salicylate 8.714%Cetalkonium Chloride 0.010%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	% w/w
Choline salicylate	8.714
Cetalkonium chloride	0.010

Excipient(s) with known effect:
Ethanol 33.45% w/w
d-Limonene, anisyl alcohol and linalool (contained in trace amounts in fragrances of star anise oil)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal gel.

Clear, colourless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of pain and discomfort of common mouth ulcers, cold sores, denture sore spots, infant teething and mouth ulcers, and sore spots due to orthodontic devices in children.

To aid healing of sore spots and ulcers due to dentures in adults and orthodontic devices in children.

4.2 Posology and method of administration

By topical application to the oral mucosa.

Adults: Using a clean finger, massage approximately one centimetre of the gel onto the sore area, not more than once every 3 hours.

Children (from four months): Using a clean finger, massage a pea size amount of gel onto the sore area, not more than once every 3 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.

Orthodontic devices: Apply to the sore area as described above, not more than once every 3 hours.

Denture irritation: Apply and leave at least 30 minutes before re-insertion of the dentures. Do not apply this product directly to the dentures.

If symptoms do not improve after 7 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

This medicine contains 46.83 mg of alcohol (ethanol) in each dose. The amount in each dose of this medicine is equivalent to less than 2 ml 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 (23 mg) in each dose, that is to say essentially 'sodium-free'.

This medicine contains fragrance with d-Limonene, anisyl alcohol and linalool.
d-Limonene, anisyl alcohol and linalool may cause allergic
reactions.
In addition to allergic reactions in sensitised patients, nonsensitised patients may become sensitised.

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 7 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 interactions

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 (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥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[1]
Gastrointestinal disorders	Not known	Stomatitis

Description of Selected Adverse Reactions

[1] 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. Healthcare professionals are asked to report any suspected adverse reactions via Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earslfort Centre, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517;
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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 alkalinisation, 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 lukotriene pathways, kinin release and nerve conduction have been proposed.

Cetalkonium chloride is a quarternary 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 (96% w/w), glycerol, levomenthol, hypromellose 4500, star anise oil (d-Limonene, anisyl alcohol, linalool), saccharin sodium and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Gel is contained in a collapsible aluminium tube with an internal lacquer, plastic neck insert and plastic tamper-evident closure.
Or
In a multi-layered plastic and aluminium tube with silver plastic tamper evident seal and plastic cap.
The 10 g and 15 g tubes are packed in a cardboard outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/001/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th March 2010
Date of last renewal: 12th March 2015

10 DATE OF REVISION OF THE TEXT

July 2021