SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bonjela

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	%w/w
Choline salicylate*	8.714
Cetalkonium chloride	0.010

*Added as choline salicylate solution prepared from:
Choline bicarbonate solution
Salicylic acid

Excipients with known effect:
Ethanol 46.83 mg/dose

Fragrances containing allergens (in star anise flavour)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of pain, discomfort and inflammation caused by common mouth ulcers, cold sores, denture and sore spots, as well as mouth ulcers, and sore spots due to orthodontic devices. To help to fight minor mouth infection and aid healing of sore spots and ulcers due to dentures and orthodontic devices.

4.2 Posology and method of administration

By topical application to the oral mucosa.

Adults and children over the age of 16: Using a clean finger massage approximately half an inch of the gel onto the sore area, not more than once every 3hours.

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

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

4.3 Contraindications

Not to be used in children and adolescents under the age of 16. This is because there is a possible association between salicylates and Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal.

Not to be used in patients suffering from active peptic ulceration.

Not to be used in patients with hypersensitivity to salicylates, Acetylsalicylic Acid (Aspirin) or other NSAIDs, or to any of the excipients.

Salicylates and Acetylsalicylic acid: doses > 100 mg/day during the third trimester of pregnancy

4.4 Special warnings and precautions for use

Label warnings: Do not exceed the stated dose. Consult your doctor or dentist before use if you are in the first or second trimester of pregnancy or when symptoms persist for more than seven days. Keep out of the reach of children.

This medicinal product 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.

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

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:

Salicylates and Acetylsalicylic acid: low doses (up to 100 mg/day):

Clinical studies indicate that doses up to 100 mg/day for restricted obstetrical use, which require specialised monitoring, appear safe.

Breast feeding:

Low quantities of salicylates and of their metabolites are excreted into the breast milk. Since adverse effects for the infant have not been reported up to now, short-term use of the recommended dose does not require suspending breastfeeding.

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) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Event
Respiratory, Thoracic and Mediastinal Disorders	Not known	Bronchospasm, and asthma1.
Immune System Disorders	Not known	Hypersensitivity

[1]Salicylates may precipitate bronchospasm and induce asthma attacks in susceptible patients.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Salicylate toxicity can result if the stated dose is exceeded.

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (5.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning. Patients should be given supportive therapy or treatment for salicylate poisoning as necessary. This may include treatment like activated charcoal, urinary alkalinisation and in severe cases haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 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 0.15 1/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.

6.1 List of excipients

Alcohol (96% v/v), glycerol, levomenthol, hypromellose 4500, star anise oil EP, sodium saccharin and purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years.

6.4. Special precautions for storage

Do not store above 25 °C

6.5 Nature and contents of container

Gel is contained in an extruded aluminium membrane 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 10g and 15g tubes are packed in a cardboard outer carton. The 3g tube is presented on a supporting card.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited

Dansom Lane

Hull

HU8 7DS

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0121

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/05/2008

10 DATE OF REVISION OF THE TEXT

20/11/2020