1. NAME OF THE MEDICINAL PRODUCT
Drujela® (Choline Salicylate 8.7%w/w & Cetalkonium Chloride 0.01%w/w) Mouth Gel
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram od Drujela® Mouth Gel contains:
Choline Salicylate ……..87.0mg
Cetalkonium Chloride ……0.1mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Semi-solid/ 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

Posology

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.
Children(from 4 months): Apply approximately half of the adult dose and rub gently on the affected area not more than once every three hours. Not more than six doses are to be applied within 24 hours.
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 under four months.
Contraindicated in patients suffering from peptic ulcer.

Hypersensitivity to salicylates.

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 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

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

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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

Pharmacodynamic effects

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. Pharmaceutical particulars

6.1 List of excipients

Choline Salicylate solution(50%)
Cetalkonium Chloride
Menthol Crystals
Hypromellose(methocel) E4m Premium EP
Glycerin
Ethanol 96%
Star Anise Oil
Sodium Saccharin
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30 °C. Protect from light and moisture.

6.5 Nature and contents of container
Tube of 10 grams mouth gel.

6.6 Special precautions for disposal and other handling

No Special requirements.

7.0 Applicant/Manufacturer

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