Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Teejel Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The gel contains 8.7 % w/w Choline Salicylate and 0.01 % w/w of Cetalkonium Chloride.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oromucosal Gel
Clear, colourless gel with an odour of alcohol/aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical analgesic and antiseptic in the management of pain and minor infections in and around the mouth, including oral ulcers, infant teething, stomatitis.

4.2 Posology and method of administration

Adults and older children:
Approximately 1cm (½ inch) of gel should be massaged onto the affected area.

Children (aged 4 months to 2 years):
Approximately 0.5cm (¼ inch) of gel should be massaged onto the affected area.

The hands should be cleansed before applying the cream. The treatment may be repeated every 3 to 4 hours as required.

4.3 Contraindications

Use in persons hypersensitive to salicylates.

4.4 Special warnings and precautions for use

1. If under the doctor's care or taking other medication, consult a doctor before using this product.
2. If there is no response to treatment, consult the doctor.
3. Avoid excessive use in infants and young children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Safe provided recommended dose is not exceeded.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

4.9 Overdose

Overdose with choline salicylate

Mild overdose: Symptoms include dizziness, sweating, nausea and vomiting, deafness, tinnitus, headache and mental confusion.

Severe overdose: Hyperventilation, fever, restlessness, ketosis, respiratory alkalosis and metabolic acidosis.

Patients with mild overdose should have their stomach emptied and be encouraged to drink plenty of fluids. The patients with more severe intoxication (plasma salicylate levels above $500mgl^{-1}$ in adults or $300mgl^{-1}$ in children), acidaemia must be corrected by infusion of sodium bicarbonate and then forced alkaline diuresis may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Teejel Gel contains two active ingredients, choline salicylate and cetalkonium chloride. Choline salicylate has analgesic, anti-pyretic and anti-inflammatory properties. Cetalkonium chloride is a surfactant and has bacterial activity against a wide variety of gram-negative and gram-positive bacteria found in the oral cavity and also against *Candida Albicans*.

5.2 Pharmacokinetic properties

Teejel Gel has topical action and onset of relief from pain is usually under 5 minutes and the duration of pain relief is usually in the order of 3 hours.

Plasma salicylate levels obtained after complete absorption of a single dose of Teejel Gel have been estimated at 0.5-3% of those obtained from the recommended dose of aspirin (0.3-1g four times daily).

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose
Glycerol
Ethanol 96%
Oil of Anise

Menthol
Cyclamate Sodium
Purified Water
Hydrochloric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Lacquered aluminium tube with aluminium closure and polyethylene cap containing 10 g of product.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

SSL International plc
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M41 7HA
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8 MARKETING AUTHORISATION NUMBER

PA 1138/26/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

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