

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soothake Toothache Tincture

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride	0.70 % w/w
Clove Oil	10.00 % w/w

Also contains Ethanol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gingival Solution

A colourless or pale yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the temporary relief of toothache.

4.2 Posology and method of administration

Apply as needed at four hourly intervals.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Flammable. In case of persistent pain consult your dentist.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There is no knowledge of use of this product during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None if used according to directions.

4.8 Undesirable effects

None if used according to directions.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medical product is important. It allows continued monitoring of the benefit/risk balance of the medical product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, 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

Treat as for alcohol. Massive overdoses may be hepatotoxic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96% (Alcohol)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

Do not freeze.

Store in the original packaging in order to protect from light.

6.5 Nature and contents of container

Brown glass vial with screw top containing 10 ml.

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

Dip a clean cotton bud into the product and apply to the dental cavity in the aching tooth.

7 MARKETING AUTHORISATION HOLDER

Optima Consumer Health Ltd
Concept House
Brackenbeck Road
Bradford BD7 2LW
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1904/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 April 2003

Date of last renewal: 04 April 2008

10 DATE OF REVISION OF THE TEXT

August 2014