SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dentinox Teething Gel
Infasoothe Teething Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride BP 0.33 % w/w
Cetylpyridinium Chloride BP 0.10 % w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Dental gel

Greenish yellow brown gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of pain and discomfort associated with teething in children from 5 months of age, where non-pharmacological treatments have failed to provide sufficient relief.

4.2 Posology and method of administration

Apply a pea-sized amount (0.2 grams) of Dentinox Teething Gel/ Infasoothe Teething Gel with a clean finger to the affected area of gum.

The dose may be repeated if necessary after 3 hours, up to a maximum of 6 doses in 24 hours.

Treatment should be stopped once symptoms have resolved.

Not to be used for more than 7 days.

Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

In case of vomiting, spitting or accidental ingestion, the dose should not be repeated immediately. The dose may be repeated if necessary after 3 hours.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

Contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.4 Special warnings and precautions for use

Keep all medicines out of sight and reach of children. Do not use if seal on nozzle is broken. Do not use more than one product containing lidocaine at the same time.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

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, website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

We are not aware of any problems caused by overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological Preparation, ATC code: A01AD

Cetylpyridium Chloride is a cationic disinfectant which is used for minor wounds, treating superficial infections of the mouth and preserving the product.

Lidocaine Hydrochloride is a local anaesthetic. It works by blocking nerve conduction when applied topically to nerve tissue. It acts on any part of the nervous system and on every type of nerve fibre. For example, when it is applied to the motor cortex, impulse transmission from that area stops, and when it is injected into the skin it prevents the initiation and the transmission of the sensory impulses. A local anaesthetic in contact with a nerve trunk can cause both sensory and motor paralysis in the area innervated. Many kinds of compounds interfere with conduction, but they often permanently damage the nerve cells. The great practical advantage of the local anaesthetics is that their use is reversible, their use is followed by complete recovery in nerve function with no evidence of structural damage to nerve fibres or cells.

5.2 Pharmacokinetic properties

Lidocaine produces more prompt, more intense, longer-lasting and more intense anaesthesia than does an equal concentration of procaine. Unlike procaine it is an aminoethylamide. It is an agent of choice, therefore, in individuals sensitive to ester-type local anaesthetics. Lidocaine is relatively quickly absorbed. Lidocaine is metabolised in the liver by mixed-function oxidases by dealkylation to monoethyl glycine and xylidide. The latter compound retains significant local anaesthetic and toxic activity. In man about 75% of xylidide is excreted in the urine as the further metabolite 4-hydroxy-2,6-dimethylaniline. The typical dose of Dentinox Teething gel / Infasoothe Teething Gel is about 150mg containing about 0.5mg of lidocaine hydrochloride (which approximates to about 0.1 mg/kg of bodyweight). Martindale recommends that the total dose of lidocaine hydrochloride should not exceed 200mg (3mg per kg of bodyweight). Thus, the dosage of Dentinox Teething Gel / Infasoothe Teething Gel is well within this level.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water BP	43.34 % w/w
Sorbitol Solution 70 % (non-crystallising) BP	21.00 % w/w
Xylitol HSE	14.00 % w/w
Ethanol 96% BP	9.36 % w/w
Glycerol BP	7.00 % w/w
Hydroxethylcellulose BP	2.50 % w/w
Polyoxyl 40 hydrogenated castor oils	1.00 % w/w
Pharmaceutical Liquid Flavour	0.48 % w/w
Hydroxypolyethoxy Dodecane	0.33 % w/w
Macrogol 300	0.33 % w/w
Sodium Saccharin	0.10 % w/w
Caramel E150	0.07 % w/w
Levomenthol	0.06 % w/w

6.2 Incompatibilities

None known.

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

Internally lacquered aluminium tube, the nozzle of which contains a membrane.

Pack size 10g (tube), 1 g sachet

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dendron Brands Limited
94, Rickmansworth Road
Watford
Hertfordshire
WD18 7JJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 52731/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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25/09/2025