Calgel Teething Gel

Summary of Product Characteristics Updated 15-Dec-2021 | McNeil Products Ltd

1. Name of the medicinal product

CALGEL TEETHING GEL

2. Qualitative and quantitative composition

CALGEL TEETHING GEL contains:

Lidocaine Hydrochloride Monohydrate 0.33% w/w

Cetylpyridinium Chloride 0.10% w/w

Excipients: sorbitol solution (E420), xylitol (E967), ethanol 96%, sodium (contains 0.41mg per 0.2g), benzyl alcohol, benzoic acid (E210), macrogolglycerol hydroxystearate (castor oil polyoxyl hydrogenated) and glycerol.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Topical 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.

It also has mild antiseptic properties.

4.2 Posology and method of administration

CALGEL TEETHING GEL is suitable for babies from the age of 5 months.

Apply a pea-sized amount (0.2 grams) of CALGEL 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 substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not use more than one product containing lidocaine at the same time.

The recommended dose should not be exceeded. Keep out of the sight and reach of children.

This medicine contains 29.4mg sorbitol in each 0.2g (pea sized blob). The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The castor oil may cause stomach upsets, diarrhoea, and skin reactions.

This medicine contains 19.42mg of alcohol (ethanol) in each 0.2g. The amount in 0.2g of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects. This medicine contains less than 1 mmol sodium (23 mg) per 0.2g, that is

to say essentially 'sodium-free'.

This medicine contains 0.00019mg benzyl alcohol in each 0.2g. Benzyl alcohol may cause allergic reactions and/or mild local irritation. Advise patients to not use for more than a week in young children (less than 3 years old). There is

increased risk due to accumulation in young children. High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis). Benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known.

This medicine contains 0.00077mg benzoic acid (E210) in each 0.2g. Benzoic acid may cause local irritation. May cause non-immunologic immediate contact reactions by a possible cholinergic mechanism. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

4.5 Interaction with other medicinal products and other forms of interaction

No drug interactions with CALGEL TEETHING GEL are known.

Drug interactions between intravenously administered lidocaine and oral procainamide, oral phenytoin alone or in combination with phenobarbital, primidone or carbamazepine, oral propanolol and non-potassium sparing diuretics including bumetanide, furosemide and thiazide have been reported. These drug effects are unlikely to be relevant to the use of CALGEL TEETHING GEL.

4.6 Fertility, pregnancy and lactation

The medicinal product is indicated for use in toddlers and infants, therefore use during pregnancy and lactation is not applicable.

4.7 Effects on ability to drive and use machines

Calgel Teething Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

When used according to instructions side effects would not be expected. However, isolated cases of hypersensitivity to lidocaine hydrochloride have been reported in adults and in a child over 12 years following local injection. Hypersensitivity presented in these cases as localised oedema with slight difficulty in breathing or as generalised rash.

Chamomile, a minor ingredient in the herbal flavouring agent, has been documented as causing allergic reactions. Hypersensitivity to chamomile normally manifests as breathing difficulties in atopic individuals. Anaphylactic reactions have been reported in individuals drinking herbal tea infusions containing chamomile (herbal tea asthma). Sensitised individuals may demonstrate positive skin reactions to preparations containing chamomile.

In the event of any unwanted side effects, use should be discontinued and a doctor consulted.

Post-marketing Data:

Adverse drug reactions (ADRs) identified during post-marketing experience with Cetylpyridinium/Lidocaine are included in Table 1. The frequencies are provided according to the following convention:

Very common ≥1/10

Common ≥1/100 and < 1/10

Uncommon ≥1/1,000 and <1/100

Rare ≥1/10,000, and <1/1,000

Very rare <1/10,000

Not known (cannot be estimated from the available data)

Table 1: Adverse Drug Reactions Identified During Post-Marketing Experience with Cetylpyridinium/Lidocaine Frequency Category Estimated from Clinical Trials or Epidemiology Studies	
SOC	
Frequency category	*Adverse Event Preferred Term*
Immune System Disorders	
Not known	*Hypersensitivity (including Dermatitis)*
General Disorders and Administration Site Conditions	
Not known	*Application site reactions (including Erythema)*

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Cetylpyridinium

Ingestion of cetylpyridinium in large doses may cause gastric upset and central nervous system depression. Concentrations where overdose symptoms were observed were 70 times higher than the concentrations of cetylpyridinium chloride found in this product.

Lidocaine

Systemic toxic effects with local anaesthetics (all forms of administration) may include central nervous system and cardiac effects.

No symptoms of overdosage have been identified from the analysis of post-marketing data for this product.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, local (Amides) Lidocaine combinations

ATC code: N01 BB52

Established local anaesthetic (lidocaine) for topical application.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

No additional information.

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol solution (70%) (E420)

Xylitol (E967)

Ethanol 96%

Glycerol

Hydroxyethyl cellulose 5000

Macrogolglycerol hydroxystearate (Cremophor RH 40) (castor oil polyoxyl hydrogenated)

Macrogol lauryl ether 9

Macrogol 300

Saccharin sodium

Levomenthol

Pharmaceutical liquid flavour, (containing chamomile, benzyl alcohol, and benzoic acid (E210))

Caramel (E150, containing sugars)

Citric acid monohydrate

Sodium citrate dihydrate

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years (unopened)

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

10 g collapsible, internally lacquered, aluminium tube, the nozzle of which possesses a membrane.

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. Marketing authorisation holder

McNeil Products Limited

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Buckinghamshire

HP12 4EG

UK

8. Marketing authorisation number(s)

PL 15513/0015

9. Date of first authorisation/renewal of the authorisation

04.06.99

10. Date of revision of the text

26 November 2021.

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