

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

Calgel Teething Gel (Lidocaine hydrochloride) Product Information:

Presentation:

Topical gel containing Lidocaine hydrochloride 0.33% w/w and Cetylpyridinium chloride 0.1% w/w.

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

Dosage and Administration:

Children over 5 months: apply a pea-sized amount (0.2g) of gel onto affected area of gum. The dose can be reapplied after 3 hours if necessary up to a maximum of 6 times in 24 hours. Treatment should be stopped once symptoms have resolved.

Contraindications:

Hypersensitivity to ingredients.

Precautions: Do not exceed recommended dose. Due to the presence of sucrose and sorbitol in the teething gel, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not use this medicine. Benzyl alcohol in the teething gel may cause allergic reactions. Large amounts of benzyl alcohol can build-up in your body and may cause metabolic acidosis. Benzoic acid may cause local irritation and non-immunologic immediate contact reactions. Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity. Benzoic acid may also increase jaundice in newborn babies up to 4 weeks old. Do not use for more than a week in young children (less than 3 years old). Castor oil may cause stomach upsets, diarrhoea and skin reactions.

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

Fertility, pregnancy and lactation: Not applicable.

Side effects: Not known frequency: Hypersensitivity (including Dermatitis) or Application site reactions (including Erythema).

RRP (ex-VAT): 10g £2.70

Legal category: P

PL holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG

PL Number: 15513/0015

Date of Preparation: 14 September 2021