Calgel®

Lidocaine hydrochloride/ Cetylpyridinium chloride

Composition

Active substance

Calgel® contains 0.33% w/w of lidocaine hydrochloride and 0.10% w/w of cetylpyridinium chloride.

Excipients

Sorbitol, Macrogol 300, Ethanol, Saccharin Sodium, Glycerol, Caramel, Levomenthol, Hydroxyethylcellulose 5000, Xylitol, Laureth 9, PEG-40 hydrogenated castor oil concentrate (Cremophor, RH410), Sodium citrate, Citric acid monohydrate, Herbal flavor.

Pharmaceutical form

The product is a yellowish brown coloured gel, with a characteristic odour. Smooth and free from grittiness, lumps and foreign matter.

ATC code: A01AD11

Indications

Calgel® is indicated for use in teething, acts quickly to help relieve teething pain and soothe infants' gums. It also has mild antiseptic properties.

Dosage and Administration

Route of Administration

For oromucosal use.

Adults

There are no relevant data available.

Children

Calgel® teething gel is suitable for babies from the age of 3 months.
A small quantity of teething gel, approximately 7.5mm, should be squeezed onto the tip of a clean finger and rubbed gently onto the affected area of the gum.
Application may be repeated after an interval of 20 minutes, if necessary, with up to six applications in one day.

Elderly

There are no relevant data available.

Renal impairment

There are no relevant data available.

Hepatic impairment

There are no relevant data available.

Contraindications

Calgel® is contraindicated in patients with known hypersensitivity to the product or any of its ingredients.

Warnings and Precautions

Use in children

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

Excipients

Patients with rare hereditary problems of fructose intolerance should not use this medicine.

Contains sorbitol solution 70%. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per <dose>.
Contains Castrol oil polyoxyl hydrogenated, may cause stomach upset and diarrhea.

Interactions

No drug interactions with lidocaine hydrochloride/ cetylpyridinium chloride are known.

122570

Pharma code Ref. No. 7240

Other
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 lidocaine hydrochloride/ cetylpyridinium chloride teething gel.

Pregnancy and Lactation
Fertility
There are no relevant data available.

Pregnancy
Not relevant for this product.

Lactation
Not relevant for this product.

Ability to perform tasks that require judgement, motor or cognitive skills
Not relevant for this product.

Adverse Reactions
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 normal 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.

Overdosage
Symptoms and signs
Suppression of pharyngeal sensation with concomitant effects on swallowing may result from excessive oromucosal use of lidocaine hydrochloride/ cetylpyridinium chloride.
Treatment
In the event of overdose, use should be discontinued and a doctor consulted.
Lidocaine is readily absorbed from mucous membranes.

Prescription status
To be used on prescription.

Storage conditions
Store below 25°C. Protect from light.

Shelf life:
Shelf life is 3 years.

Package:
0.33%/10% 10g gel in tube along with patient information leaflet placed in a carton box.

Manufactured by
GlaxoSmithKline Pharmaceuticals S.A., 189 Grunwaldzka street, 60-322 Poznan, Poland

Marketing Authorization Holder
Glaxo Wellcome UK Limited, Stockley Park, Middlesex, UB 11 1BT, UK

«CALGEL is trade mark of GSK group of companies»

NCDS v01

Version date : 10 March 2015

122570

Pharma code Ref. No. 7240