

**Calgel®**

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*Lidocaine hydrochloride/ Cetylpyridinium chloride*

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## Composition

### Active substance

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

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### 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.

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Other

Drug interactions between intravenously administered lidocaine and oral procainamide, oral phenytoin alone or in combination with phenobarbital, primidone or carbamazepine, oral propranolol 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 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.

## 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

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NCDS v01

Version date : 10 March 2015