SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

Calgel

Lidocaine hydrochloride/ cetylpyridinium chloride

2. Qualitative and Quantitative Composition

Active substance

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

3. Pharmaceutical form

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

4. Clinical Particulars

4.1 Therapeutic Indications

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

4.2 Posology and Method of Administration

Route of Administration

For oromucosal use.

Adults

There are no relevant data available.

Children

Calgel dental gel is suitable for babies from the age of 3 months.

A small quantity of dental gel, approximately 7.5 mm (0.22 g), 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.

4.3 Contraindications

Calgel dental gel is contraindicated in patients with hypersensitivity to lidocaine hydrochloride and/ or cetylpyridinium chloride or to any of the excipients.

4.4 Warnings and Precautions

Use in children

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

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 amount of ethanol (alcohol), less than 100mg per <dose>.
Contains Castor oil polyoxyl hydrogenated, may cause stomach upset and diarrhea.

4.5 Interactions
No drug interactions with lidocaine hydrochloride/ cetylpyridinium chloride dental 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 lidocaine hydrochloride/ cetylpyridinium chloride dental gel.

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

Fertility
There are no relevant data available.

4.7 Ability to perform tasks that require judgement, motor or cognitive skills.
Lidocaine hydrochloride/ cetylpyridinium chloride dental gel has no influence on the ability to drive and use machines.

4.8 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 generalized 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.

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency.

Frequencies are defined as:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data).

Immune System Disorders
Not known: hypersensitivity (including dermatitis)

General disorders and Administration Site Conditions

Not known: application site reactions (including erythema).

4.9 Overdosage

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 postmarketing data for this product.
Management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group
Anaesthetics, local (Amides); Lidocaine combinations

ATC code: N01 BB52

Mechanism of Action Pharmacodynamic effects
Calgel dental gel is a oromucosal analgesic preparation while lidocaine itself is a local anaesthetic when applied to mucosal surfaces.
Cetylpyridinium chloride has antiseptic properties.

5.2 Pharmacokinetics

Absorption
Lidocaine is readily absorbed from mucous membranes.

Distribution
Lidocaine is bound to plasma proteins, includingα1-acid glycoprotein (AAG). The extent of binding is variable but is about 66%. Plasma protein binding of lidocaine depends in part on the concentrations of both lidocaine and AAG. Any alteration in the concentration of AAG can greatly affect plasma concentrations of lidocaine.

Metabolism
Lidocaine is largely metabolised in the liver. Metabolism in the liver is rapid and about
90% of a given dose is dealkylated to form monoethylglycinexylidide and glycinexylidide.
Elimination
Lidocaine metabolites are excreted in the urine with less than 10% of unchanged lidocaine.

Prescription status
To be used on prescription.

5.3 Preclinical Safety Data
N/A

6. Pharmaceutical Particulars

6.1 Excipients

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.

6.2 Incompatibilities

N/A

6.3 Shelf life:

Shelf life is 3 years.

6.4 Storage conditions

Store below 25º C. Protect from light.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal

N/A

7. Manufacturer (name, address, company)

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

8. Marketing Authorization Holder

GlaxoWellcome UK Limited, Stockley Park, Middlesex, UB 11 1BT, UK

9. Date of final revision of the text

Version date: 18 April 2017