

Package leaflet: Information for the user

Calgel 3.3 mg/g + 1 mg/g teething gel lidocaine hydrochloride and cetylpyridinium chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Calgel is and what it is used for
2. What you need to know before you use Calgel
3. How to use Calgel
4. Possible side effects
5. How to store Calgel
6. Contents of the pack and other information

1. What Calgel is and what it is used for

Relieving the pain of teething in babies.

The lidocaine in Calgel has a local anaesthetic effect. It relieves the pain of teething and soothes the gums. Cetylpyridinium chloride has an antiseptic effect.

2. What you need to know before you use Calgel

Do not use Calgel

- if you are allergic to lidocaine hydrochloride, cetylpyridinium chloride, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Calgel if your child has:

- decreased blood volume (hypovolemia), any heart disease (including congenital heart disease, inflammation of the heart muscle (myocarditis), heart disease (cardiomyopathy), slow heart rate (bradycardia), heart failure),
- apnoea,
- if you have been told by your doctor that your child has intolerance to some sugars, talk to your doctor before using this medicine.

Only use on the gums. Not to be used on damaged or bleeding gums.

Pregnancy and breast-feeding

The medicine is indicated for use in children and babies; therefore, this medicine is not applicable for use during pregnancy and breast-feeding.

Driving and using machines

The medicine has no effect on reaction speed.

Other medicines and Calgel

Tell your doctor or pharmacist if your child is taking or has recently taken any other medicines.

Interaction with other medicines has not been observed.

Calgel contains alcohol (ethanol), sorbitol, macrogolglycerol hydroxystearate, sodium and fragrances containing propylene glycol, benzyl alcohol, benzoic acid, glucose, sucrose, invert sugar

This medicine contains 20.12 mg of alcohol (ethanol) per dose, equivalent to 91.46 mg/g (9.15% w/w). The alcohol content of this medicine is less than 3 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine does not have a significant effect.

This medicine contains 32.34 mg sorbitol per dose, equivalent to 147 mg/g. Sorbitol is a source of fructose. If you have been told by your doctor that your child has an intolerance to some sugars, or if your child has been diagnosed with rare hereditary problems of fructose intolerance (which prevents the body from breaking down fructose), you should consult your doctor before taking this medicine. This medicine contains macrogolglycerol hydroxystearate, which may cause stomach irritation and diarrhea.

This medicine contains less than 1 mmol (23 mg) sodium per dose, ie essentially 'sodium-free'.

This medicine contains 0.04 mg of propylene glycol per dose, equivalent to 0.19 mg/g.

This medicine contains 0.0002 mg of benzyl alcohol per dose, equivalent to 0.00096 mg/g. Benzyl alcohol may cause allergic reactions. Do not use in infants (under 3 years of age) for more than one week without the advice of a doctor or pharmacist. Talk to your doctor or pharmacist if your child has liver or kidney disease. Benzyl alcohol in large quantities can accumulate in the body and cause side effects (so-called "metabolic acidosis").

This medicine contains 0.0008 mg benzoic acid per dose, equivalent to 0.004 mg/g.

If you have been told by your doctor that your child has an intolerance to some sugars, contact your doctor before taking this medicinal product.

Chamomile, forming a small part of the herbal flavouring, can cause allergic reactions. Patients sensitive to chamomile can develop skin symptoms or breathing difficulties.

3. How to use Calgel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Squeeze a small amount (7.5 mm) of gel onto a washed fingertip and apply gently on the gums. The application can be repeated if necessary. Wait for at least 2 hours before applying the next dose. The gel must not be used more than six times per day.

If you use more Calgel than you should

Do not exceed the recommended amounts! If you have accidentally used more Calgel than you should, immediately stop the treatment and ask your doctor or pharmacist for advice.

For more information, talk to your doctor or pharmacist.

If you forget to use Calgel

Do not use a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In very rare cases (less than 1 case per 10,000 users), the following side effects have been reported:

- hypersensitivity (incl. dermatitis),

- application site reactions (incl. erythema, or redness),
- gum disorders,
- swollen lip,
- lip or tongue discolouration,
- oral herpes,
- rash,
- somnolence (sleepiness),
- psychomotor hyperactivity,
- elevated body temperature,
- hypersensitivity.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calgel

Do not store at a temperature higher than 25 °C.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Calgel contains

The active ingredients are:

- lidocaine hydrochloride and cetylpyridinium chloride. 1 g of gel contains 3.3 mg of lidocaine hydrochloride and 1 mg of cetylpyridinium chloride.
- The other ingredients are: sorbitol solution (non-crystallising) (E420); xylitol (E967), ethanol 96%, glycerol (E422), hydroxyethyl cellulose 5000, macrogolglycerol hydroxystearate (Cremophor RH40), macrogollauryl ether, macrogol 300, sodium sachharine (E954), levomenthol, flavouring (contains propylene glycol, benzyl benzoate, benzoic acid, benzyl alcohol, chamomile), ammonium caramel (E150c) (glucose, sucrose, invert sugar), citric acid monohydrate (E330), sodium citrate dihydrate (E331), purified water.

What Calgel looks like and contents of the pack

Calgel is a yellowish transparent soft, chamomile-flavoured sugar-free gel.

Aluminium tube with a nozzle and polypropylene screw cap. The 10 g tube is packaged in a cardboard carton.

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