



- This product can be used to help relieve pain and discomfort associated with teething, when other non-medical methods such as massaging of the gums or use of teething rings do not provide necessary relief.
- This medicine is suitable for most babies and children over 5 months. **Do not give this medicine, if your child is under 5 months old.**
- **Do not give it to anyone on this list:**
  - Not to anyone who has ever had a **bad reaction** to any of the ingredients. *See section 6* ►
- **Follow the dosage instructions carefully.** These are shown in the table. *See section 3* ►

**Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

## 1 What the medicine is for

This product can be used to help relieve pain and discomfort associated with teething, in children from 5 months of age, when other non-medical methods such as massaging of the gums or use of teething rings do not provide necessary relief. It also contains cetylpyridinium chloride (a mild antiseptic) to help prevent infection.

## 2 Before giving the medicine to your child

This medicine is suitable for most children, but a few children should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### **X Do not give your child this medicine...**

- if your child is under **5 months old**.
- If your child has ever had an **allergic reaction** to the product, chamomile, or any of the ingredients.

If this applies, **get advice from a doctor or pharmacist without using CALGEL®.**

- Do not use at the same time as other products containing lidocaine.

### **⚠ Talk to your doctor or pharmacist...**

- If your child has an **intolerance to some sugars**.

If this bullet point applies now or in the past, speak to a **doctor or pharmacist**.

### **If your child is using any other medicines**

No interactions with other medicines are currently known.

### **⚠ If you are pregnant or breast-feeding**

The following advice is included in case an older child or adult is taking this medicine.

- If you are pregnant or breast-feeding only use this medicine on the advice of your doctor.

### **⚠ Some of the ingredients can cause problems**

- This medicine contains 29.4mg sorbitol in each 0.2g (pea sized blob). Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HF), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- This medicine contains 19.42mg of alcohol (ethanol) in each 0.2g. The amount in 0.2g of

this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

- Xylitol may have a laxative effect.
- The castor oil may cause stomach upsets, diarrhoea, and skin reactions.
- This medicine contains less than 1 mmol sodium (23 mg) per 0.2g, that is to say essentially 'sodium-free'.
- This medicine contains 0.00019mg benzyl alcohol in each 0.2g. Benzyl alcohol may cause allergic reactions and/or mild local irritation. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. If you are taking this medicine, ask your doctor or pharmacist for advice if your child has a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.
- This medicine contains 0.00077mg benzoic acid (E210) in each 0.2g. Benzoic acid may cause local irritation. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

## 3 How to use this medicine


- For topical use only.
- Do not give more than the dose stated below.

### **i Babies under 5 months**

Do not give this medicine, if your child is under 5 months old.

turn over ►

## **i** Babies from 5 months and over

Age	Dose
<b>Babies and toddlers 5 months and over</b>	 0.2g Apply a pea sized blob of gel (see circle shown above), to a clean fingertip and spread gently onto the sore area of the gum.

- If necessary, repeat the dose after 3 hours.
- Do not use more than 6 times in one day (24 hour period).
- Stop treatment when your child's symptoms settle.
- Do not use for more than 7 days for each teething episode.
- If your child's symptoms worsen, do not improve after 7 days of treatment or you are concerned that your child is unwell, talk to a health care professional.
- If your child vomits, spits or swallows the medicine, do not use any more product immediately. Wait 3 hours before using the medicine again.
- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you to.
- Do not give more medicine than the label tells you to.
- You should check with your doctor or pharmacist if you are not sure.

## **A** If anyone has used too much

If anyone uses more CALGEL® Teething Gel than they should, or if large quantities of the gel are accidentally swallowed, contact a doctor or your nearest Accident Emergency Department (Casualty) taking this leaflet and pack with you, even if the child seems well.

## 4 Possible side-effects

CALGEL® Teething Gel can have side-effects, like all medicines, although these are rare and usually mild.

**If your child experiences any of the following, stop using the medicine and seek immediate medical help:**

- Swelling of the mouth, gums or tongue.
- Difficulty in breathing.
- Rash.
- Inflammation of the skin.
- Reddening of the skin.

### Reporting of the side-effects

If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects you can help provide more information on the safety of this medicine.

## 5 Storing this medicine

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

Do not store above 25°C.

Keep the tube tightly closed.

Store in the original package.

Do not use your medicine after the date shown as an expiry date on the packaging.

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 Further information

### What's in this medicine?

**The active ingredients in CALGEL® Teething Gel are:**

Lidocaine Hydrochloride Monohydrate 0.33% w/w and Cetylpyridinium chloride 0.10% w/w.

**Other ingredients are:** Sorbitol solution (70%) (E420), xylitol (E967), ethanol 96%, glycerol, hydroxyethyl cellulose 5000, macrogolglycerol hydroxystearate (castor oil polyoxyyl hydrogenated), macrogol lauryl ether 9, macrogol 300, saccharin sodium, levomenthol, pharmaceutical liquid flavour (containing chamomile, benzyl alcohol, and benzoic acid (E210)), caramel (E150, containing sugars), citric acid monohydrate, sodium citrate dihydrate and purified water.

Sorbitol content 15% w/w.

### What the medicine looks like

CALGEL® Teething Gel is a yellowish-brown gel, available in 10 g tubes.

**Product Licence holder** is McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

**Manufacturer:** Delpharm Orléans, 5 avenue de Concyr, 45071 Orléans, Cedex 2, France.

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CALGEL® Teething Gel is a registered trade mark.

