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**ANBESOL<sup>®</sup> TEETHING GEL**

Lidocaine Hydrochloride, Chlorocresol  
and Cetylpyridinium Chloride

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**PATIENT INFORMATION LEAFLET**

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

- Keep this leaflet. You may wish 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.

What is in this leaflet:

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

**1. What Anbesol Teething Gel is and what it is used for**

Anbesol Teething Gel contains 1.0%w/w of lidocaine hydrochloride, 0.1%w/w of chlorocresol and 0.02%w/w of cetylpyridinium chloride.

Lidocaine hydrochloride is a local anaesthetic which works by stopping the sensation of pain. Chlorocresol and cetylpyridinium chloride kill bacteria.

Anbesol Teething Gel is used to help relieve pain and discomfort associated with **teething**, in children from 5 months of age, when other non-medicinal methods such as massaging of the gums or use of teething rings do not provide necessary relief.

The product may also be used for the temporary relief of pain caused by recurrent **mouth ulcers** and **denture irritation**.

**2. What you need to know before you use Anbesol Teething Gel**

**Do not use Anbesol Teething Gel:**

- If you are allergic to lidocaine hydrochloride, chlorocresol, cetylpyridinium chloride, other anaesthetics similar to lidocaine or any of the other ingredients in this medicine (listed in Section 6).
- You have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Anbesol Teething Gel:

- If you have open wounds or damaged areas in the lining of your mouth as this may result in too much of the active ingredients being absorbed.
- If symptoms continue for more than 7 days or recur frequently, speak to your pharmacist, doctor or dentist.

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

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

Do not use more Anbesol Teething Gel than recommended (as listed in Section 3) as this may result in the active ingredients being absorbed into the body causing serious side effects, such as convulsions (fits).

### **Other medicines and Anbesol Teething Gel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines as they may interfere with Anbesol Teething Gel:

- Other anaesthetics or medicines similar to lidocaine for example antiarrhythmic drugs such as mexiletine which are used to control abnormal heartbeats
- Erythromycin a type of antibiotic used to treat bacterial infections
- Itraconazole a type of antifungal medicine used to treat fungal infections
- Antiarrhythmic drugs such as amiodarone which are used to control abnormal heartbeats
- Cimetidine used to treat stomach ulcers or heartburn
- Beta-blockers used to treat heart conditions, high blood pressure or migraine
- Calcium chloride used for the treatment of hypocalcaemia or as a food additive
- Codeine phosphate used to treat pain, diarrhoea or relieve coughs
- Diamorphine hydrochloride a painkiller used to treat severe pain
- Paveretum used to treat moderate to severe pain and to calm you before an operation
- Quinine hydrochloride used to treat malaria or leg cramps
- Methylcellulose used to treat constipation
- Non-ionic surfactants such as Cetomacrogol 1000 and polysorbate 80 which are used in medicines, foods and cosmetics

### **Pregnancy, fertility and breast-feeding**

If you are pregnant, breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

If you are breast-feeding small amounts of the active ingredient lidocaine will pass into your breast milk but in such small quantities that it should not harm your baby if this medicine is used as directed.

### **Driving and using machines**

Anbesol Teething Gel is unlikely to affect your ability to drive or use machines.

### **Important information about some of the ingredients**

This medicine contains chlorocresol and the azo dye Ponceau 4R (E124) which may cause allergic reactions in sensitive individuals.

This medicine contains 128 mg of alcohol (ethanol) in each pea-sized amount (0.2 g), which is equivalent to 640 mg/ g (63.9% w/w). The amount in 0.2 g of this medicine is equivalent to 3 ml beer or 2 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

## **3. How to use Anbesol Teething Gel**

### **Adults and the elderly:**

- Apply a small amount of gel to a clean fingertip and spread gently onto the affected area.
- Two applications straight away will normally be enough for temporary pain relief.
- Do not apply more frequently than every 3 hours.

### **Babies teething and children:**

- Apply a pea sized blob of gel (see circle shown here), to a clean fingertip and spread gently onto the affected area.



- 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.

### **If you use more Anbesol Teething Gel than you should**

If anyone used more Anbesol Teething Gel than they should, or if large quantities of the gel are accidentally swallowed, contact your doctor or your nearest Accident and Emergency department, taking this leaflet and pack with you.

## **4. Possible side effects**

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

- Allergic reactions (eg difficulty breathing, rash or itch).
- Some people have reported suffering from ulcers.
- Dermatitis (inflammation of the skin that can cause red, itchy and scaly skin).

### **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 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. How to store Anbesol Teething Gel**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.
- 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 Anbesol Teething Gel contains**

Anbesol Teething Gel contains the active ingredients; lidocaine hydrochloride 1.0%w/w, chlorocresol 0.1%w/w and cetylpyridinium chloride 0.02%w/w.

It also contains alcohol, clove oil, glycerol, hydroxypropyl cellulose, sodium saccharin, Ponceau 4R (E124) and purified water.

### **What Anbesol Teething Gel looks like and contents of the pack**

Anbesol Teething Gel is a soft pink clear gel for oromucosal use supplied in a tube containing 10g.

Marketing Authorisation Holder:

Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Manufactured by: Conforma N.V., Zenderstraat 10, B-9070 Destelbergen, Belgium.

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