



ANBESOL® Liquid

Lidocaine Hydrochloride, Chlorocresol
and Cetylpyridinium Chloride

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

1. What Anbesol Liquid is and what it is used for?

Anbesol Liquid contains 0.9%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 Liquid 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 by **adults, children and the elderly** for the temporary relief of pain caused by recurrent **mouth ulcers** and **denture irritation**.

2. What you need to know before you use Anbesol Liquid

Do not use Anbesol Liquid:

- 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).
- If your child is under 5 months old.
- At the same time as other products containing lidocaine.

Do not use more Anbesol Liquid 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).

Warnings and precautions

Talk to your doctor or pharmacist before using Anbesol Liquid:

- 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.

Other medicines and Anbesol Liquid

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 Liquid:

- 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 Liquid 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 dyes amaranth (E123) and sunset yellow (E110) which may cause allergic reactions.

This medicine contains 151 mg of alcohol (ethanol) in each dose (0.25 ml), which is equivalent to 604 mg/ ml (65.6% w/v). The amount in 0.25 ml of this medicine is equivalent to 4 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 Liquid

Follow these instructions carefully and never change the dose yourself. Do not exceed the stated dose.

Adults and the Elderly:

- Cover the mouth of the bottle with a clean fingertip, invert once and return the bottle to the upright position.
- Apply Anbesol Liquid using the fingertip, undiluted, to the affected area
- Two applications of Anbesol Liquid straight away, will normally be enough to obtain pain relief.
- If necessary, repeat the application after 3 hours.

Babies Teething and Children:

- Cover the mouth of the bottle with a clean fingertip, invert once and return the bottle to the upright position. This equals to a dose of 0.25 ml of Anbesol liquid.
- Apply Anbesol Liquid using the fingertip, undiluted, to the affected area.
- If necessary, repeat the application after 3 hours.
- Do not use more than 6 times in one day (24-hour period).
- If your child vomits, spits or swallows the medicine, do not use any more product immediately. Wait 3 hours before using the medicine again.

- 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.
- Do not use for more than 7 days for each teething episode.
- Stop treatment when your child's symptoms settle.
- 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 Liquid than you should:

If anyone used more Anbesol Liquid than they should, or if large quantities of the liquid 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 mouth 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, 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, 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 Liquid

- 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 bottle 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 pack and other information

What Anbesol Liquid contains

Anbesol Liquid contains the active ingredients; lidocaine hydrochloride 0.90%w/w, chlorocresol 0.10%w/w and cetylpyridinium chloride 0.02%w/w.

It also contains alcohol (96%), menthol, glycerol, caramel colouring (comprised of quinoline yellow (E104), amaranth (E123), sunset yellow (E110) and green S (E142) and purified water.

What Anbesol Liquid looks like and contents of the pack

Anbesol Liquid is a clear yellow liquid for oromucosal use supplied in bottles containing 5ml, 10ml or 15ml.

Not all pack sizes may be marketed.

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.

This leaflet was last revised in March 2021.

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Changes made to PIL

Issue Number	Job number/reason for change	Competent Authority Approval Date	Change Made By
001	Change of ownership 11-081	21.7.11	Sue Rogers
002	11-175 BROMI label & leaflet to remove Wrafton Labs	24.8.11	Sue Rogers
003	Grouped Type II & Type IB variation following CCDS creation (11-274) 12-030 12-035 RFI dated 30.3.12 RFI dated 19.4.12 12-176 BROMI to correct spelling mistake	9.5.12 9.5.12 Implemented immediately	Sue Rogers
004	12-239 Tech transfer – change in manufacturer name and address	4/7/2013	Ann Ruddock
005	13-381 change of pack size from 6.5 ml to 5 ml	31/10/14	Ann Ruddock
006	14-234 Update of SmPC and PIL for ADR warnings	16/03/2015	LAF
007	18-526 Risk minimisation measures to oral products containing lidocaine used in children – Variations to SPC, PIL & packaging after MHRA-CHM opinion	04/09/2018	Joanna Tsigou
008	18-0904 Introduction of 10ml pack size	12-03-2019	Joanna Tsigou
009	20-0516 Update to ethanol warning in line with excipients guidelines	07-07-2021	LW

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