
ANBESOL™ Anaesthetic Antiseptic Oromucosal solution

Lidocaine hydrochloride 0.90%w/w, Chlorocresol 0.10%w/w,
Cetylpyridinium Chloride 0.02%w/w

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine because it contains important information for 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

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1. What Anbesol Anaesthetic Antiseptic Oromucosal Solution is and what it is used for

Anbesol Anaesthetic Antiseptic Oromucosal solution contains 0.90% w/w of lidocaine hydrochloride, 0.10% 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 Anaesthetic Antiseptic Oromucosal solution is used for the relief of pain caused by mouth ulcers and sore gums.

Anbesol Anaesthetic Antiseptic Oromucosal solution can be used by adults, the elderly and adolescents and children aged 10-18 years old.

2. What you need to know before you use Anbesol Anaesthetic Antiseptic Oromucosal solution

Do not use Anbesol Anaesthetic Antiseptic Oromucosal solution:

- 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 this medicine 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.

Do not use more Anbesol Anaesthetic Antiseptic Oromucosal Solution than recommended (refer to 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 Anaesthetic Antiseptic Oromucosal Solution

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 Anaesthetic Antiseptic Oromucosal Solution:

- 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 (low calcium levels) or as a food additive
- Codeine phosphate used to treat pain, diarrhoea or relieve coughs
- Diamorphine hydrochloride a painkiller used to treat severe pain
- Papaveretum 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 Anaesthetic Antiseptic Oromucosal solution 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 151mg 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 less than 4 ml beer or 2 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Anbesol Anaesthetic Antiseptic Oromucosal solution

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

Adults, the Elderly and adolescents and Children aged 10-18 years old:

- Apply undiluted to the affected area using a clean fingertip.
- Two applications of the solution straight away will normally be enough for pain relief.
- Do not apply more frequently than every 3 hours, or as directed by the doctor or dentist.

If you still have symptoms after 3 days, speak to your doctor or dentist.

Do not persist with any of this solution if results seem unsatisfactory, except on doctor's advice.

If you use more Anbesol Anaesthetic Antiseptic Oromucosal solution than you should:

If anyone used more Anbesol Anaesthetic Antiseptic Oromucosal solution than they should, or if large quantities of the solution 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 can cause side effects, although not everybody gets them.

- Allergic reactions (e.g. 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 HPRÁ Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anbesol Anaesthetic Antiseptic Oromucosal solution

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine 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 Anaesthetic Antiseptic Oromucosal solution contains

The active substances are lidocaine hydrochloride 0.90%w/w, chlorocresol 0.10%w/w, cetylpyridinium chloride 0.02%w/w.

The other ingredients are ethanol 96% w/v, levomenthol, glycerol, caramel colouring (comprised of quinoline yellow E104, amaranth E123, sunset yellow E110 and green S E142) and purified water.

What Anbesol Anaesthetic Antiseptic Oromucosal solution looks like and contents of the pack

Anbesol Anaesthetic Antiseptic Oromucosal solution 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 and Manufacturer

Marketing Authorisation Holder: Alliance Pharma (Ireland) Limited,
United Drug House, Magna Drive, Dublin, D24 X0CT, Ireland

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

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