

ANBESOL® ADULT STRENGTH GEL

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

1. What Anbesol Adult Strength Gel is and what it is used for

Anbesol Adult Strength Gel contains 2.0%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 Adult Strength Gel is used for temporary relief of pain caused by recurrent **mouth ulcers** and **denture irritation** for adults and children over 12 years.

2. What you need to know before you use Anbesol Adult Strength Gel**Do not use Anbesol Adult Strength 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 Adult Strength 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 more Anbesol Adult Strength 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).

Children

Do not give this medicine to children under the age of 12 years.

Other medicines and Anbesol Adult Strength 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 Adult Strength 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 Adult Strength Gel is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients

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

This medicinal product contains 66.605% ethanol (alcohol), i.e. up to 0.760 mg per ml, equivalent to 15.2 ml beer, 6.3 ml wine per dose which may be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high risk groups such as patients with liver disease, or epilepsy.

3. How to use Anbesol Adult Strength Gel

Adults, the elderly and children 12 years and over:

- Apply a small amount of Anbesol Adult Strength Gel to affected area with a clean fingertip.
- One application should be sufficient to obtain temporary pain relief.
- Do not apply more frequently than every 3 hours.

If you use more Anbesol Adult Strength Gel than you should:

If anyone used more Anbesol Adult Strength 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anbesol Adult Strength Gel

- Keep 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 Adult Strength Gel contains

Anbesol Adult Strength Gel contains the active ingredients; lidocaine hydrochloride 2.0%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 Adult Strength Gel looks like and contents of the pack

Anbesol Adult Strength 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: Wrafton Laboratories Limited, Wrafton, Braunton, EX33 2DL, UK.

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