



DENTINOX[®]

TEETHING GEL

Lidocaine hydrochloride, Cetylpyridinium chloride



PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet, you may need to read it again. If you need more information or advice speak to your health visitor, pharmacist or doctor.

IN THIS LEAFLET:

1. What Dentinox Teething Gel is and what it is used for
2. Before you use Dentinox Teething Gel
3. How you use Dentinox Teething Gel
4. Possible side effects
5. How to store Dentinox Teething Gel
6. Further information

1. WHAT DENTINOX TEETHING GEL IS AND WHAT IT IS USED FOR

Dentinox Teething Gel contains the active ingredients lidocaine and cetylpyridinium. Lidocaine is one of a group of medicines called local anesthetics, which numb pain. Cetylpyridinium is an antiseptic that is used to treat minor wounds and minor infections of the mouth.

Dentinox Teething Gel can be 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.

2. BEFORE YOU USE DENTINOX TEETHING GEL

You should not use Dentinox Teething Gel if your baby is allergic (hypersensitive) to lidocaine, cetylpyridinium or any other ingredients (see list of ingredients in Section 6). See a doctor at once if you notice the following: rash, swelling of the face, neck, tongue or throat (severe allergic reaction).

DO NOT USE Dentinox Teething Gel if the seal on the nozzle is broken.

Taking other medicines

Please tell your doctor or pharmacist if your baby is taking, or has recently taken, any other medicines, including medicines obtained without a prescription.

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.

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF DENTINOX TEETHING GEL

Dentinox Teething Gel contains sorbitol. If you have been told by your doctor that your baby **has an intolerance to some sugars**, contact your doctor before using this product.

This medicine also contains small amounts of ethanol, less than 100mg per dose.

3. HOW YOU USE DENTINOX TEETHING GEL

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).

DOSAGE SIZE



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.

4. POSSIBLE SIDE EFFECTS

There are no known side effects from Dentinox Teething Gel.

Reporting of side effects. If your baby experiences any side effects, consult 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 DENTINOX TEETHING GEL

Dentinox Teething Gel should be kept out of the reach and sight of children. Do not store above 25°C.

Do not use Dentinox Teething Gel after the expiry date as indicated on the box.

The expiry date refers to the last day of the month.

Medicine should not be disposed of in waste-water or with household waste.

Ask your pharmacist what you should do with medications you no longer need.

These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dentinox Teething Gel contains: The active substances are lidocaine hydrochloride 0.33% w/w and cetylpyridinium chloride 0.10% w/w. The other ingredients are: Sorbitol solution 70% (non-crystallising), xylitol, ethanol, glycerol, hydroxethylcellulose, polyoxyl 40 hydrogenated castor oils, pharmaceutical liquid flavour, hydroxypolyethoxydodecane, macrogol 300, sodium saccharin, caramel (E150), levomenthol and purified water.

What Dentinox Teething Gel looks like and contents of the pack:

Dentinox Teething Gel is available in aluminium tubes containing 10g.

Marketing Authorisation Holder and Manufacturer: Dendron Brands Limited, 94 Rickmansworth Road, Watford, Hertfordshire, United Kingdom, WD18 7JJ.

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