



DENTINOX[®]



INFANT COLIC DROPS

Activated dimeticone

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 Infant Colic Drops are and what are they used for
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1. WHAT DENTINOX INFANT COLIC DROPS ARE AND WHAT ARE THEY USED FOR

Dentinox Infant Colic Drops contain the active ingredient activated dimeticone. This product belongs to a group of medicines called surface active substances. Dentinox Infant Colic Drops work by helping to release trapped wind. This helps to relieve tummy pain and indigestion.

Dentinox Infant Colic Drops are for the gentle relief of wind and griping pains in babies.

This medicine can be used from birth onwards.

2. WHEN NOT TO GIVE DENTINOX INFANT COLIC DROPS

Do not give Dentinox Infant Colic Drops if your baby is being treated for a thyroid disorder; seek advice from your doctor instead.

Do not give Dentinox Infant Colic Drops if you think your baby might be allergic (hypersensitive) to dimeticone or any other ingredients of Dentinox Infant Colic Drops (listed in section 6 of this leaflet).

Taking other medicines:

If your baby is being treated with levothyroxine for a thyroid disorder, using Dentinox Infant Colic Drops might reduce the amount of this type of medicine that is absorbed, weakening the effect of their treatment.

Important information about some of the ingredients of Dentinox Infant Colic Drops

Dentinox Infant Colic Drops contain **sucrose**. If you have been told by your doctor that your baby has an **intolerance to some sugars**, contact your doctor before giving these drops. This medicine may be harmful to the teeth. Dentinox Infant Colic Drops also contains methyl, ethyl, propyl parahydroxybenzoates (**E218, E214, E216**), which may cause allergic reactions (possibly delayed).

3. HOW TO GIVE DENTINOX INFANT COLIC DROPS

Shake bottle before use. Dosage: 2½ml (one measured dose of the syringe) should be given with or after each feed. Dentinox Infant Colic Drops can be added to the baby's bottle or given orally directly from the syringe. Maximum 6 doses per day. After use, rinse the syringe with warm water and dry. Not suitable for steam sterilisation.

If you give more Dentinox Infant Colic Drops than you should contact your health visitor, pharmacist or doctor for advice.

If you have any further questions on the use of this product, speak to your health visitor, pharmacist or doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dentinox Infant Colic Drops can cause side effects, although these do not affect everybody.

If you notice any signs of allergy stop using the product and seek medical advice.

There are no known side effects from Dentinox Infant Colic Drops.

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 INFANT COLIC DROPS

Dentinox Infant Colic Drops should be kept out of the sight and reach of children.

Do not store above 25 °C.

Do not use Dentinox Infant Colic Drops after the expiry date as indicated on the box and bottle. 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 Infant Colic Drops contain: The active substance is activated dimeticone 42mg/5ml. The other ingredients are: purified water, sucrose, carbomer, dill oil, sodium hydroxide, methyl parahydroxybenzoate E218, ethyl parahydroxybenzoate E214, and propyl parahydroxybenzoate E216.

What Dentinox Infant Colic Drops look like and contents of the pack:

Dentinox Infant Colic Drops are available in a 100ml round plastic bottle with a 2.5ml syringe.

Marketing Authorisation Holder and Manufacturer:

DDD Limited, 94 Rickmansworth Road, Watford, Hertfordshire, United Kingdom, WD18 7JJ.

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