

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dentinox Infant Colic Drops

21 mg/2.5 ml oral suspension

Activated Dimeticone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- If you need more information or advice on the medicine or your baby's condition, or if the symptoms persist, speak to your health visitor, pharmacist or doctor.

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1. What Dentinox Infant Colic Drops are and what they are 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 works by helping to release trapped wind. This helps to relieve tummy pain and indigestion.

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

This medicine can be used from birth onwards.

2. What you need to know before you use 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.

Please tell your doctor or pharmacist if your baby is taking or has recently taken any other medicines.

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

Dentinox Infant Colic Drops contains **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 methylhydroxybenzoate E218, ethyl hydroxybenzoate E214 and propyl hydroxybenzoate E216 which may cause allergic reactions (possibly delayed).

3 How to use Dentinox Infant Colic Drops

Shake bottle before use.

Dosage: 2.5 ml should be given with or after each feed.

A 2.5 ml Syringe is provided with

this pack. Dentinox Infant Colic Drops can be added to the baby's bottle or given orally using the spoon provided. Maximum 6 doses per day.

If you use 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 medicine, 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. However, if you think this medicine is causing the baby any problems speak to your health visitor, pharmacist or doctor.

You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

5. How to store Dentinox Infant Colic Drops

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 as indicated on the carton and bottle after EXP. 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. Contents of the pack and other information

What Dentinox Infant Colic Drops contains: The active substance is activated dimeticone 21mg/2.5ml. The other ingredients are: purified water, sucrose, carbomer, dill oil, sodium hydroxide, methylhydroxybenzoate E218, ethylhydroxybenzoate E214 and propylhydroxybenzoate E216.

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

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

Marketing Authorisation Holder:

Phoenix Labs, Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, Co. Meath, Ireland.

Manufacturer:

LABORATORI FUNDACIÓ DAU, C/C, 12-14, Pol. Ind. Consorci Zona Franca, 08040 Barcelona, Spain.

7. About infant colic

When babies feed they produce gastric juices and acids. These acids can curdle milk which can trap air bubbles and lead to colic. The air bubbles may stop the natural movement of food down the gut. Dentinox Colic Drops gently disperses the air bubbles. The released air can then rise to the top of the baby's tummy and become a satisfying burp.

This leaflet was last revised in March 2025.