

Laleham PIL text

PACKAGE LEAFLET: INFORMATION FOR THE USER

infacol[®]

Simeticone 40 mg per 1 ml Oral Suspension

Read all of this leaflet carefully because it contains important information for your baby.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any side effects occur, talk to your doctor, pharmacist or nurse. See section 4.
- You must talk to a doctor if your baby's symptoms worsen or do not improve.

What is in this leaflet:

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

1. WHAT INFACOL IS AND WHAT IT IS USED FOR

Your baby's medicine is called Infacol. It is an antiflatulent which means that it helps to bring up wind or air trapped in the tummy. Infacol is given to babies to relieve griping pain, infant colic or wind due to trapped air. The pain associated with colic may be caused by the build-up of small gas bubbles trapped in your baby's tummy. Simeticone, the active ingredient in Infacol, helps all the little trapped gas bubbles join into bigger bubbles which your baby can easily bring up as wind.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE INFACOL

- Do not give Infacol if you think your baby might be allergic (hypersensitive) to simeticone or any of the other ingredients of this medicine (listed in section 6).
- Do not give Infacol and get advice from a doctor if your baby is being treated for a thyroid disorder.

Warnings and precautions

Other medicines and Infacol

If your baby is being treated with levothyroxine for a thyroid disorder using Infacol might reduce the amount of this type of medicine that is absorbed and weaken the effect of their treatment.

Infacol contains methyl hydroxybenzoate (E218) and propyl hydroxybenzoate (E216)

These may cause allergic reactions (possibly delayed).

3. HOW TO USE INFACOL

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Dose

Infacol is very simple to give, even when your baby is crying. The recommended dose is one dropper full (0.5ml) which should be given before each feed.

If after 3 or 4 days your baby's colic still seems to be upsetting, you can double the dose to two droppers full (1ml). This may be especially useful at night, before the evening feed.

Infacol should be used for several days to achieve the best results, as treatment may show a progressive effect. Continued use may help to prevent a further build up of wind. You can continue to use Infacol for several weeks. However, if despite having increased the dose to two droppers full there is no improvement, or your baby seems to be getting worse, speak to your health visitor or doctor.

Administration

- Gently shake the bottle.
- Draw up one dropper full by squeezing the bulb twice. Let the excess Infacol on the outside of the dropper run back into the bottle.
- Administer the dose by squeezing the bulb and releasing the Infacol onto the back of your baby's tongue.

Do not use the dropper for other medicines. Keep it for Infacol only.

If you give more Infacol than you should

If your baby (or an adult) accidentally swallows a large quantity of Infacol (such as a whole bottle full) it is highly unlikely to do any harm.

However, if the person who has taken it feels or looks unwell, you should seek medical advice.

If you forget to give Infacol

Do not worry if you forget to give your baby one or more doses. Simply give the next dose before the baby's next feed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Simeticone, the active ingredient in Infacol, is not absorbed into the baby's body and is very unlikely to harm your baby. It is very unusual for Infacol to cause any side-effects.

Reporting of side effects

If your baby gets 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE INFACOL

Keep this medicine out of the sight and reach of children.

Do not use Infacol after the expiry date which is stated on the bottle and carton after the letters 'EXP'. The expiry date refers to the last day of that month.

Once opened, use within 28 days. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Infacol contains

The active ingredient is simeticone. Each 1ml of oral suspension contains 40mg.

The other ingredients are saccharin sodium, hypromellose, orange flavour, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216) and purified water.

What Infacol looks like and contents of the pack

Infacol is an orange-flavoured, off-white, oral suspension (liquid). This product is available in packs containing 50ml, 55ml, 75ml, 85ml or 100ml of Infacol..

Not all pack sizes may be marketed.

The Marketing Authorisation Holder is

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The Manufacturer is

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