

INFACOL[®]
Simeticone 40mg per 1 ml Oral Suspension

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any side effects occur, please tell your doctor or pharmacist.

In this leaflet:

1. What is Infacol and what is it used for?
2. Before you give Infacol
3. How to give Infacol
4. Possible Side Effects
5. How to store Infacol
6. Further 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. It can be given from birth onwards. 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. BEFORE YOU GIVE INFACOL

Do not give Infacol and get advice from a doctor if your baby is being treated for a thyroid disorder.

Do not give Infacol if you think your baby might be allergic (hypersensitive) to any of the ingredients of Infacol (see section 6 of this leaflet).

Using other medicines

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.

3. HOW TO GIVE INFACOL

Follow the instructions about when and how to use the product. You should check with your doctor or pharmacist if you are not sure.

Dose

Infacol is very simple to give, even when your baby is crying. The normal 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. Methyl and propyl hydroxybenzoates (E218, E216), which are also ingredients in Infacol, may cause allergic reactions (possibly delayed). If you think your baby has any side effects from taking this medicine, please tell your doctor, health visitor or pharmacist.

5. HOW TO STORE INFACOL

Keep out of the reach and sight 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Infacol contains

The active ingredient is simeticone at a concentration of 40mg/ml.

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). Each full bottle contains 50ml of Infacol, which is enough for up to 100 doses.

The Marketing Authorisation Holder is:

Forest Laboratories UK Ltd.
Riverbridge House
Anchor Boulevard
Crossways Business Park
Dartford
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DA2 6SL

The Manufacturers are:

Witham Contract Manufacturing Ltd
Stepfield
Witham
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This leaflet was last approved in May 2012

To listen to or to request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product Name

Infacol 40mg/ml Oral Suspension

Reference Number

0108/0100

This is a service provided by the Royal National Institute for Blind People.