infacol®

Simeticone 40 mg per 1 ml Oral Suspension

PACKAGE LEAFLET: INFORMATION FOR THE USER

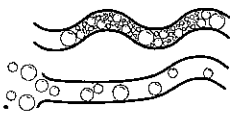
Read all of this leaflet carefully because it contains important information for your baby.

- 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 baby's symptoms worsen or do not improve.
- If any side effects occur, please tell your doctor or pharmacist.

In this leaflet:

1. What Infacol is and what it is 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 if you think your baby might be allergic (hypersensitive) to any of the ingredients of Infacol (see section 6 of this leaflet).

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.

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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.

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

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 Limited
Dartford
Kent DA2 6SL
UK

The Manufacturer is
William Ransom plc
Stepfield
Witham
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UK

This leaflet was last approved in July 2009

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	**Reference Number**
Infacol 40mg/ml Oral Suspension	0108/0100

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

Forest

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