

TEVA

UK

Eastbourne
Artwork
Origination

Dim's Changed?:	No
Length:	210 mm
Width:	160 mm
Depth:	-
Foil Width:	-

Colours Used:

Template & Code Areas

PANTONE® 199C

PANTONE® Cool Grey7C

**INSTRUCTIONS FOR USE (IFU)**

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

- Keep this IFU. 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 unwanted effects occur, please tell your doctor or pharmacist. See section 4.

In this instructions for use:

1. Indication
2. Mechanism of action
3. Instructions for use
4. Warnings
5. Storage and expiry date

Main ingredient:

Simeticone 40mg per 1ml Oral Suspension

Also contains:

Purified Water, Hypromellose, Orange Flavour, Saccharin Sodium, Methyl Hydroxybenzoate (E218) and Propyl Hydroxybenzoate (E216).

This product is available in bottles containing 50ml, 55ml, or 85ml of Infacol. Not all bottle sizes may be marketed.

1. Indication

INFACOL oral suspension is indicated for the treatment of colic and griping pain in babies and young children. The pain associated with colic may be caused by the build-up of small gas bubbles trapped in the baby's tummy. Infacol helps release trapped wind. It can be given from birth onwards, and may be given for an unlimited period.

2. Mechanism of action

INFACOL contains simeticone at a concentration of 40mg per 1ml as main ingredient. Simeticone is an antiflatulent which helps release wind trapped in the tummy, through burping or flatulence. The simeticone helps the little trapped gas bubble join into bigger bubbles which your baby can easily release as wind.

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3. Instructions for use

First, shake the bottle. Draw up one dropper full by squeezing the rubber bulb twice. Wipe any excess on the outside of the dropper into the bottle. To administer, squeeze the bulb and release the INFACOL onto the back of the baby's tongue.

Dosage:

One dropper full (0.5ml) given before each feed. If after 3 or 4 days your baby's colic still seems to be upsetting, this may be increased temporarily to two droppers full (1ml). INFACOL should be used for several days to achieve the best results. Continued usage may help to prevent a further build-up of wind.

4. Warnings


Simeticone INFACOL is inert and not absorbed into the body. INFACOL is not known to cause any unwanted effects. Methyl and propyl hydroxybenzoates may cause allergic reactions (possibly delayed). If you think your baby may be allergic to any of the ingredients, ask your doctor or health visitor before giving INFACOL.

If symptoms do not improve seek medical advice.

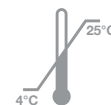
5. Storage and Expiry Date

Keep INFACOL out of reach and sight of children, in a safe place.
Do not use after the expiry date printed on the bottle and carton.
Use within 28 days after opening.

Date of last revision of leaflet
02-2018

 Merckle GmbH, Graf-Arco-Str. 3
89079 Ulm, Germany
EAS2377a

CE 0482



ZINC Ref: **EAS2377a LEA INFACOL 85ml ORAL SUSP LALEHAM**Version: **3****22 March 2018****TEVA****UK***Eastbourne
Artwork
Origination*

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Template & Code Areas

PANTONE® 199C**PANTONE® Cool Grey7C**

PL Number(s), -
 MA Holder & Packer: **Packed at Laleham.**

Trackwise Parent: -

Trackwise Child: -

Reason for revision: **New item. V2: Updates from proof-reading. V3: Tech amends.**SKU (s): **32029290**

EAN Code: -
 Perforated: **No**
 Shelf Ready: -

Pharma Code: -
 Edge Code: -
 PIP Code: -
 Third party Code: -
 Packing Site Code: -

Fonts: **Yummo,
 Fira,
 Helvetica.**

Base Font Size: **8.17 pt**

For Eastbourne packed components only:
 Please refer to the latest version of the full base material specification:
 92653, 92655, 92651

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Artwork Drawn by:
Artwork 3

Artwork Checker:
 Sign & Date:

Packing Site /Technical Approval:
 Sign & Date:

Approved by Regulatory for submission to the
 authorities / Internal Approval / implementation;
 Sign & Date:

Internal/Final Approval and/or implementation from
 the MA holder confirming full approval for release of
 components; Sign & Date:

APPROVED
Zinc