SUMMARY OF PRODUCT CHARACTERISTICS

1  NAME OF THE MEDICINAL PRODUCT

INFACOL

2  QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:
Simeticone 40mg/ml

Excipients with known effect:
Methyl Hydroxybenzoate (E218) 0.18% w/v
Propyl Hydroxybenzoate (E216) 0.02% w/v

For the full list of excipients, see section 6.1.

3  PHARMACEUTICAL FORM

Oral suspension

A white/off white opaque suspension free from particulates.

4  CLINICAL PARTICULARS

4.1 Therapeutic indications

An antiflatulent for the relief of griping pain, colic or wind due to swallowed air.
4.2 Posology and method of administration

Posology

For adults and elderly:
Not applicable.

For infants:
20mg (0.5ml), one dropper full is administered before each feed. If after 3 or 4 days, symptoms do not improve, the dose may be increased to 40mg (1ml) two droppers full.

Treatment with Infacol may provide a progressive improvement in symptoms over several days.

Method of administration
Oral. Shake before use.

4.3 Contraindications

Hypersensitivity to Simeticone or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The parahydrobenzoates used in infacol may cause delayed hypersensitivity reactions.

If symptoms persist, seek medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Levothyroxine may bind to simeticone. Absorption of levothyroxine may be impaired if Infacol is given concurrently to infants treated for thyroid disorders.
4.6 Fertility, Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

In the event of deliberate or accidental overdosage, treat symptoms on appearance.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Simeticone is an anti-flatulent with ATC code A03AX13.

Physiologically the active ingredient is a chemically inert, non-systemic gastric defoaming agent that works by altering the elasticity of interfaces of mucus-embedded bubbles in the gastrointestinal tract.
The gas bubbles are thus broken down or coalesced and in this form gas is more easily eliminated through eructation or passing flatus.

5.2 Pharmacokinetic properties

Simeticone is not absorbed from the gastrointestinal tract.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin Sodium
Hypermellose
Orange flavour
Methyl Hydroxybenzoate (E218)
Propyl Hydroxybenzoate (E216)
Purified Water

6.2 Incompatibilities

None stated.

6.3 Shelf life

As packaged for sale : 3 years
After first opening : 28 days.
6.4 Special precautions for storage

Do not store above 25°C).

6.5 Nature and contents of container

High-density polyethylene bottle fitted with a low-density polyethylene dropper and evoprene teat containing 50ml, 55ml, 75ml, 85ml and 100ml of liquid.

6.6 Special precautions for disposal

Not stated.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Brampton Road,
Hampden Park,
Eastbourne,
East Sussex
BN22 9AG,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2321
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29th October 1986 / 20 January 1997

10 DATE OF REVISION OF THE TEXT

02/10/2018