Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Infacol 40mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose of suspension contains 20 mg of Simeticone.

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
Orange – flavoured, colourless, translucent suspension.

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). If necessary this may be increased to 40mg (1ml).

Method of administration
Infacol should be administered orally before each feed.

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

Methyl and propyl hydroxybenzoates (E218 and E216) which are also ingredients in Infacol 40mg/ml Oral Suspension, may cause allergic reactions (possible delayed).

If symptoms persist, seek medical advice.

4.5 Interaction with other medicinal products and other forms of interactions

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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 gastro-intestinal tract. It is not absorbed from the gut.

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

None stated.

5.3 Preclinical safety data

There are no pre-clinical 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
Hypromellose
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^{o}C.

6.5 Nature and contents of container

High density polyethylene bottle fitted with a low density polyethylene dropper and evoprene teat containing 50 ml of liquid.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Tosara Pharma Limited
Unit 146
Baldoyle Industrial Estate
Grange Road
Baldoyle
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0247/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 February 1991

Date of last renewal: 27 February 2006

10 DATE OF REVISION OF THE TEXT

March 2019 CRN008RWK