Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dentinox Infant Colic Drops 21 mg/2.5 ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated Dimeticone 21.0 mg/2.5 ml.

Excipients: also includes sucrose, 0.396 g per 2.5 ml

Methylhydroxybenzoate (E218), Ethylhydroxybenzoate (E214) and Propylhydroxybenzoate (E216)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension
A colourless to translucent white viscous emulsified suspension with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of infant colic.

4.2 Posology and method of administration

½ teaspoon (2.5 ml) with or after each feed. May be added to the infant's bottle or given orally using the spoon provided.
Maximum 6 doses per day.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

Shake before use.
This product contains parahydroxybenzoates, which may cause allergic reactions (possibly delayed).
Keep all medicines out of reach of children.
If symptoms persist obtain 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 Dentinox Infant Colic Drops are 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 known.
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

From the literature it would appear that all the silicone will be excreted unchanged and that there was no increase of urinary silicate output or of absorption of the silicone.

It was concluded that the Activated Dimeticone carried no significant carcinogenic hazard, and that no other significant toxic effect attributable to Activated Dimeticone has been observed.

Overdosage may prove a problem with diabetics because of the sugar content.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Excessive swallowing of air results in collection of gas in the intestine. This can be the result of too rapid eating, excessive use of a pacifier (dummy), finger sucking or yelling. When the swallowed air is in the intestine, bubbles are formed, which makes it more difficult for the gas to pass through the intestine canal, resulting in abdominal distension and pain. Activated Dimeticone is a surface active substance which changes the surface tension of the intestinal mucus. Thus, the air bubbles burst and the gas is released.
The elimination of the gas, air or foam from the gastro-intestinal tract, relieves abdominal distension and dyspepsia.

5.2 Pharmacokinetic properties

Activated Dimeticone is chemically inert and is not absorbed. Its effect is local on the intestinal contents.

No side effects from the substance are reported from the literature.

From the toxicity trials undertaken by Dow Corning, it has been demonstrated in the rat that all the Dimeticone was recovered in the faeces and that there was no increase in urinary silicate output.

In four human subjects given 376.5 mg of Activated Dimeticone, twice daily for 10 days, it was found that there was no increase in their urinary silicate output and no evidence of absorption of the silicone.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Sucrose
Carbomer
Dill Oil
Sodium Hydroxide

Methyl hydroxy benzoate (E218)
Ethyl hydroxy benzoate (E214)
Propyl hydroxy benzoate (E216).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

100ml HDPE round bottle with a white polyethylene jay cap tamper evident closure.
The product also includes a 2.5 ml oral dosing syringe.

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

Shake before use.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath.
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 October 1983

Date of last renewal: 5 October 2008

10 DATE OF REVISION OF THE TEXT

April 2021