

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Dentinox Infant Colic Drops

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated Dimeticone 21.0 mg/2.5 ml.

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Oral suspension

A colourless 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 ½ ml) with or after each feed. Maybe added to the infant's bottle or given orally directly by spoon.  
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 sucrose-isomaltase insufficiency should not take this medicine.

##### 4.4 Special warnings and precautions for use

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 interaction

None known.

##### 4.6 Pregnancy and lactation

Not applicable.

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

None known.

#### **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 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 376.5mg 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**

Deionised water  
Sucrose  
Carbomer  
Dill Oil  
Sodium Hydroxide

Nipasept (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 25°C.

## **6.5 Nature and contents of container**

100ml HDPE round bottle with a jay cap tamper evident closure.

## **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**

DDD Limited  
94 Rickmansworth Road  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 302/3/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 5 October 1983

Date of last renewal: 5 October 2003

## **10 DATE OF REVISION OF THE TEXT**

February 2006