Only for the use of medical professionals  $\mathbf{Simet}^{\mathbb{R}}$ Simethicone

## **Description**

**Simet**® Paediatric Drops is a preparation of Simethicone which has antiflatulent and anticolic property. Simethicone relieves the discomfort of infant gas frequently caused by air swallowing or by certain formulas or foods. The clinical use of Simethicone is based on its antifoaming properties. The defoaming action of Simethicone relieves flatulence by dispersing and preventing the formation of mucus-surrounded gas pockets in the GI tract. It acts in the stomach and intestines to change the surface tension of gas bubbles, enabling them to coalesce; thus, gas is freed and eliminated more easily by belching or passing flatus.

#### Indication

Simet<sup>®</sup> is indicated

- For treating the symptoms of infant colic.
- For relief of the painful symptoms of excess gas in the digestive tract.
- As an adjunct in the treatment of many conditions in which gas retention may be problem such as: Post operative gaseous distention, air swallowing, functional dyspepsia, peptic ulcer, spastic or irritable colon or diverticulitis.
- For the management of accidental ingestion of foaming detergents.
- Prior to gastroscopy to enhance visualization and prior to radiography of the intestine to reduce gas shadows.

#### **Dosage and Administration**

**Simet**<sup>®</sup> drops can be taken after meals and at bedtime or as directed by the physician. It is better to shake the bottle well before each use. For infants, the drops can be mixed with one ounce of cool water, infant formula or other suitable liquids for use in small children.

Infant under 2 years of age: Simet<sup>®</sup> 0.3 ml (20 mg) 4 times daily. Maximum daily dose is Simet<sup>®</sup> 3.6 ml (240 mg).

**Children 2-12 years of age: Simet**<sup>®</sup> 0.6 ml (40 mg) 4 times daily. Maximum daily dose is **Simet**<sup>®</sup> **7**.5 ml (500 mg).

**Adults: Simet**<sup>®</sup> 0.6 ml- 1.2 ml (40-80 mg) 4 times daily. Maximum daily dose is **Simet**<sup>®</sup> **7**.5 ml (500 mg).

#### **Precautions**

Simethicone drops should not exceed 12 doses per day except under the advice of a physician. Keep the medicine out of the rich of children.

### **Side Effects**

Simethicone is physiologically inert and no adverse effect has been noted after oral ingestion.

# **Use in Pregnancy & Lactation:**

*Pregnant women*: No data are available to suggest any harmful effects. *Lactating mother*: Excretion of Simethicone in breast milk has not been established, and would be most unlikely.

### **Drug Interactions**

There is no evidence that Simethicone modifies the effect of other drugs. The defoaming effect of Simethicone is reduced by antacids such as aluminum hydroxide and magnesium carbonate, which absorb the silicone.

## Over dosage

If the baby accidentally swallows a large quantity of Simethicone (such as a whole bottle full) it is unlikely to do any harm. However, if the parents feel his/her baby looks unwell, medical advice should be sought.

### **Pharmaceutical Precautions**

Store in a cool and dry place. Protect from light.

#### **Presentation**

**Simet**® Paediatric Drops: Each ml drop contains Simethicone USP 67 mg.

### **Package Quantities**

Each bottle contains 15 ml drops with a plastic dropper.

Registered Trade Mark

