

Flacol[®]

Simethicone USP

COMPOSITION

Flacol[®] Paediatric Drops: Each ml drop contains 67 mg Simethicone USP. **Flacol[®]** Tablet: Each chewable tablet contains Simethicone USP 40 mg.

PHARMACOLOGY

Flacol[®] (Simethicone) is used as an antifatulent to relieve symptoms commonly referred to as gas including upper GI bloating, pressure, fullness or stuffed feeling. The clinical use of **Flacol[®]** is based on its antifoaming properties. Its antifoaming action relieves flatulence by dispersing and preventing the formation of mucous surrounded

PRECAUTION

Keep the medicine out of the reach of children.

DRUG INTERACTION

There is no evidence that Simethicone modifies the effect of other drugs.

USE IN PREGNANCY AND 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.

INDICATION

1. *Flatulence, abdominal distention, fullness, gas and windy colic:* **Flacol[®]** is an excellent and effective antifatulent. It is used for relief of the painful symptoms of excess gas in the digestive tract. Such gas is frequently caused by excessive swallowing of air or by eating foods that disagree. **Flacol[®]** drop is especially used in infants, acts in the stomach and intestines. Thus **Flacol[®]** enables freeing and eliminating the gas more easily by belching or passing flatus. 2. *Large bowel preparation:* Addition of **Flacol[®]** to a polyethylene glycol bowel preparation produces symptomatic improvement prior to investigation in the management of accidental ingestion of foaming detergents. 3. *Treatment of poisoning:* **Flacol[®]** has an anecdotal use as an antifoaming agent in the management of accidental ingestion of foaming detergents.

DOSAGE AND ADMINISTRATION

Take after meals and at bedtime. Can be given with infant's feeds. Shake the bottle well before each use. *Children less than 2 years of age:* 20 mg (0.3 ml **Flacol[®]** Paediatric Drops) 4 times daily up to 240 mg/day (3.6 ml **Flacol[®]** Paediatric Drops). *Children 2-12 years of age:* 40 mg (0.6 ml **Flacol[®]** Paediatric Drops) 4 times daily. *Adults:* 40-125 mg. 0.6 ml-1.9 ml **Flacol[®]** Paediatric Drops; 4 times daily, up to 500 mg/day (7.5 ml **Flacol[®]** Paediatric Drops) or 1-3 **Flacol[®]** chewable tablets; 4 times daily, up to 500 mg/day (12 **Flacol[®]** chewable tablets).

gas pockets in the GI tract. **Flacol[®]** 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. **Flacol[®]** aids in the elimination of gas from the GI tract and can be used to reduce postoperative gas pains. **Flacol[®]** can also be used prior to gastroscopy to enhance visualization and prior to radiography of the intestine to reduce gas shadows.

SIDE EFFECT

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

STORAGE CONDITION

Should be stored in cool and dry place, protected from light.

HOW SUPPLIED

Flacol[®] Paediatric drops: Bottle containing 15 ml drops with plastic dropper. **Flacol[®]** Tablet: Each box contains 50 chewable tablets.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
Bangladesh