

Flacol[®]

Simethicone USP

Composition

Flacol[®] Paediatric Drops: Each ml drop contains 67 mg Simethicone USP.

Pharmacology

Flacol[®] (Simethicone) is used as an antiflatulent 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 antifoam properties. Its defoaming action relieves flatulence by dispersing and preventing the formation of mucous surrounded 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.

Indication

1. Flatulence, abdominal distention, fullness, gas and windy colic

Flacol[®] (Simethicone) is an excellent and effective antiflatulent. 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[®]** (Simethicone) 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[®]** (Simethicone) to a polyethylene glycol bowel preparation produces symptomatic improvement prior to investigation in patients undergoing colonoscopy,

3. Treatment of poisoning

Flacol[®] (Simethicone) 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**[®] drops) 4 times daily up to 240 mg (3.6 ml Flacol [®] drops)/day.

Children: 2-12 years of age

40 mg (0.6 ml **Flacol**[®] drops) 4 times daily.

Adults

40-80 mg (0.6 ml-1.2 ml **Flacol**[®] drops) 4 times daily, up to 500 mg (7.5 ml **Flacol**[®] drops)/day.

Side effect

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

Precaution

Do not exceed 12 doses per day except under the advice and supervision of a physician. 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.

Storage Condition

Should be stored in well-closed bottle, protected from light, at a temperature not exceeding 30^oC.

How supplied

Flacol[®] Paediatric Drops: Bottle containing 15 ml preparation with a plastic dropper.

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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