

Disflatyl® Drops sugar-free



Composition

Active ingredient: 40 mg Simethicone (activated dimethylpolysiloxane)

Excipients: Preservatives: benzoic acid (E-210), sodium benzoate (E-211); saccharin sodium; flavourings; emulsion excipients ad 1ml equivalent to 27±3 drops.

Disflatyl® Drops contain artificial sweetener and are therefore also suitable for diabetics.

Galenic Form and Quantity of Active Substance per Unit

1ml solution contains 40 mg of Simethicone.

Indications and Usage

Symptomatic treatment of all types of excessive gas accumulation or formation in the gastrointestinal tract such as flatulence, meteorism, aerophagy, gastro cardiac symptom complex, postoperative meteorism.

To prepare for endoscopic, radiological or sonographic investigations of the stomach and/or bowel.

Dosage and Administration

Symptomatic treatment

Adults: Take 25-50 drops, possibly with a little fluid, after every meal and before retiring to bed.

Schoolchildren: Take 15-20 drops, possibly with a little fluid, after every meal and before retiring to bed.

Babies and infants: About 10-15 drops 2-3 times a day in the bottle or (up to 6 years of age) after meals.

Preparation for stomach and/or bowel investigation

50 drops 3-4 times a day on the two preceding days, and 50 drops each when fasting on the morning of the day of investigation and immediately before the investigation.

Note: Shake the bottle thoroughly before use.

Contraindications

Ileus, obstructive gastrointestinal disorders. Known hypersensitivity to one or more of the above mentioned ingredients.

Special Warnings and Precautions

No special precautionary measures are necessary.

Interactions

No interactions have been reported up to now.

Pregnancy, Lactation

Controlled studies have not been carried out either on animals or on humans (see "Preclinical Data"). Since the active ingredient is not absorbed there are not expected to be any risks for the foetus, nor is it expected to enter breast milk.

Effects on Ability to Drive and Use Machines

No relevant studies have been carried out.

Since simethicone is an inert substance which is not absorbed there are no expected effects on the ability to drive or use machines.

Undesirable Effects

No unwanted effects have been observed.

Since the simethicone in Disflatyl Drops is not absorbed in the gastrointestinal tract and is excreted unchanged, no unwanted effects are expected.

Overdosage

No toxic effects from overdose have been reported.

Properties and Effects

ATC-Code: A04AX13

Mechanism of action:

Simethicone is an atoxic silicone-based surface-active substance and foam suppressant. It breaks down the gas bubbles which occur in flatulence and meteorism in a purely physical way by changing the surface tension. The gas which is liberated can then be absorbed and/or escape in a natural way.

Pharmacokinetics

Simethicone acts exclusively on the surface of the gas bubbles and is not absorbed by the mucous membranes.

Preclinical Data

Simethicone is an inert substance which is not absorbed in the gastrointestinal tract. Results of published studies in mice and rats gave no evidence that the drug may have carcinogenic effects. Furthermore published studies in mice and rabbits did not show any evidence of embryotoxic or teratogenic effects.

Other Information

Stability

Protect from heat (store below 30°C) and do not use after the date identified by "EXP." on the container.

Pack Sizes

Dropping bottle 30 ml

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Medicine: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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