For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Simethicone Oral Suspension USP

(Brand Name: MEFTAL-SPAS NEO Drops)

2. Qualitative and Quantitative Composition

Each ml contains:

Simethicone IP ……..…..……40 mg

Syrup base ……..q.s.

With **Dill Oil** and **Fennel Oil**

3. Dosage Form

Dosage Form: Oral Liquid (Suspension)

4. Clinical Particulars

4.1 Therapeutic Indications

MEFTAL-SPAS NEO Drops are used for the relief of infantile colic, gastrointestinal tract (GI) spasm, flatulence and abdominal discomfort due to excess gas formation.

4.2 Posology and Method of Administration

Usual Pediatric Dose:

Age based dosing:

Infants less than 2 years: 20 mg orally after meals and at bedtime as needed (Maximum dose: 240 mg/day)

Children greater than 2 years: 40 mg orally after meals and at bedtime as needed (Maximum dose: 480 mg/day)

Weight-based dosing:

Under 10.9 kg: 20 mg orally after meals and at bedtime as needed (Maximum dose: 240 mg/day)

Over 10.9 kg: 40 mg orally after meals and at bedtime as needed (Maximum dose: 480 mg/day)

Usual Adult Dose: 40-125 mg orally 3 times a day as needed after meals or at bedtime (Maximum dose: 500 mg/day)

4.3 Contraindications

MEFTAL-SPAS NEO Drops are contraindicated in the following:

- Known hypersensitivity to simethicone or to any excipient of the formulation.

4.4 Special Warnings and Precautions for Use

No special warnings and precautions are needed. Simethicone is apparently non-toxic; no adverse effects reported.

4.5 Drug Interactions

There are no known reported drug interactions with simethicone.

4.6 Use in Special Populations

Pregnant Women

Simethicone: Pregnancy Category C.

Animal studies with simethicone have not revealed maternal or fetal toxicity. Simethicone is not expected to harm an unborn baby. However, due to lack of safety in human trials, this product should be used with caution during pregnancy and only under medical supervision.

Lactating Women

Studies have not been conducted to determine if simethicone is excreted in human milk. However, due to the fact that simethicone is not absorbed systemically, it seems unlikely that simethicone would be excreted in the milk of breast-feeding women.

Paediatric Patients

For dosage in infants & children, please refer ‘Posology and Method of Administration’ section.

4.7 Effect on Ability to Drive and Use Machines

Not applicable

4.8 Undesirable Effects

Simethicone does not have any serious side effects. Simethicone may cause mild diarrhoea, nausea.

4.9 Overdose

Simethicone is apparently nontoxic; no adverse effects reported.

Pharmacological Properties

5.1 Mechanism of Action

Simethicone

Simethicone produces anti-flatulent effect by decreasing the surface tension of gas bubbles, causing them to combine into larger bubbles in the stomach. The gas bubbles are then broken or coalesced and in this form, the gas is more easily eliminated through belching or passing flatus.

5.2 Pharmacodynamic Properties

Simethicone

Simethicone is an anti-flatulent agent. Simethicone does not reduce the quantity of gas in the digestive tract, it only increases the rate at which it exits the body. Simethicone does not prevent the formation of gas from swallowed air or from being created by intestinal bacteria.

5.3 Pharmacokinetic Properties

Simethicone

Simethicone is physiologically inert and not systemically absorbed. Simethicone undergoes minimal systemic absorption. Similarly, the body does not metabolize simethicone. It is not known to interfere with gastric secretion or nutrient absorption.
Excretion: Feces (as unchanged drug); complete excretion within 24-48 hour

5. Nonclinical Properties

6.1 Animal Toxicology

Simethicone

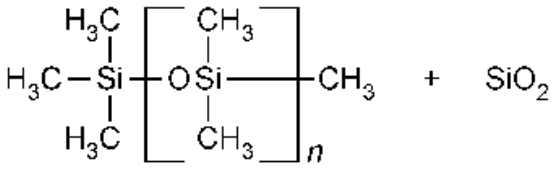
The LD50 of acute oral toxicity of simethicone to rats is greater than 2,008 mg/kg body weight and the 90-day feeding of simethicone did not cause any abnormalities in the indices.
Other toxicological data is not available for simethicone.

6. Description

MEFTAL-SPAS NEO Drops is Off white coloured viscous flavoured suspension.
Each ml of MEFTAL-SPAS NEO Drops contains 40 mg of simethicone for oral administration.

Simethicone

Simethicone, an antiflatulent agent, is a mixture of polydimethylsiloxane and hydrated silica gel. Simethicone is a gray, translucent, viscous liquid insoluble in water and alcohol.
Chemical Name: Dioxosilane;methoxy-dimethyl-trimethylsilyloxysilane.
Molecular Weight: 238.46 g/mol.
Molecular Formula: $C_6H_{18}O_4Si_3$.
Structural Formula:



Inactive ingredients (excipients) of MEFTAL SPAS-NEO Drops Xanthan Gum, Sodium Benzoate, Methyl Paraben, Propyl Paraben, Sucrose, Dill Oil, Fennel Oil & Citric Acid Monohydrate.

Dill Oil

Dill oil helps in reducing abdominal pain, preventing fungal and bacterial growth and relieves spasms. It supports digestion and overall gastrointestinal health and provides powerful antioxidant action.

Fennel Oil

Fennel oil reduces the muscle cramps in the gut and increase the stomach and intestine motility to push food through the digestive system.

7. Pharmaceutical Particulars

7.1 Incompatibilities

None known.

7.2 Shelf-life

24 Months

7.3 Packaging Information

15 ml PET bottle with 1 ml dropper.

7.4 Storage and Handling Instructions

Store at a temperature not exceeding 30°C.
Protect from light.
Shake well before use.
Keep out of reach of children.

8. Patient Counseling Information

Administration Instructions

- Instruct patients/caregivers to ensure the prescribed dose of MEFTAL SPAS-NEO Drops is taken as directed.
- Shake well before each use.

9. Details of Manufacturer

Akums Drugs & Pharmaceuticals Ltd.
Plot No. 22, Sector - 6A, I.I.E., SIDCUL,
Ranipur, Haridwar - 249 403, Uttarakhand.

10. Details of Permission or License Number with Date

Mfg. Lic. No.: 123/UA/2007. Date of Product Permission: 17/05/2022.

11. Date

November 2022

Marketed by:
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.