

1. Name of the Medicinal Product

Colicaid Drops

2. Quality and Quantitative Composition

Simethicone Use: Simethicone Emulsion USP (30%) (Contains 5% Process Excess)	40 mg (133.334 mg)
Dill Oil BP (Contains 20% Excess)	0.005 mL (4.5125 mg)
Fennel Oil USP-NF (Contains 20% Excess)	0.0007 mL (0.6741 mg)

3. Pharmaceutical Form

Off- white coloured, sweet, pleasantly flavoured with dill oil and fennel oil, easily re-dispersible viscous liquid.

4. Clinical Particulars

4.1 Therapeutic indications

Desired aid in infant colic with benefits of Simethicone, Dill oil and fennel oil in relieving infantile colic, gripping pain, flatulent dyspepsia, gaseous distension and regurgitation.

4.2 Posology and method of administration

Posology:

INFANTS (Below 6 months): 5-10 drops 4 times daily, 15 minutes before feed
INFANTS (6-12 months): 10-20 drops 4 times daily, 15 minutes before feed
CHILDREN (over 1 year): 20-25 drops 4 times daily, 15 minutes before meal Or as directed as physician.

Method of administration:

Oral

4.3 Contraindications

Colicaid Drops is contraindicated in patients with hypersensitivity to Simethicone or any other contents of Colicaid Drops.

4.4 Special warning and precautions for use

Use calibrated dropper provided in this pack. Replace cap tightly after each use.

4.5 Interaction with other medicinal products and other forms of interactions Not available **4.6 Pregnancy and lactation**

Not applicable

4.7 Effects on ability to drive and use machine

Not applicable

4.8 Undesirable effects

Free from side effects of Dicyclomine like Apnoea, dryness of mouth, blurred vision, and sedation and reduced bronchial secretion.

4.9 Overdose

Discontinue use. Seek immediate medical advice.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: NA

ATC Code: NA

Simethicone changes surface tension of gas bubbles and causes collapse of foam bubbles, thus allowing easier passage of gas and preventing gas pockets in gastrointestinal tract.

5.2 Pharmacokinetic Properties

Excretion: Feces (as unchanged drug); complete excretion within 24-48 hr.

5.3 Preclinical safety Data

The ingredients are well established, and well documented in published scientific literature, worldwide.

6. Pharmaceutical Particulars

6.1 List of excipients

- Sodium Methyl paraben BP
- Sodium Propyl paraben BP
- Sucrose BP (Crystalline)
- Xanthan Gum USP-NF
- Purified Water BP
- Sodium Citrate BP, Dihydrate
- Citric Acid Monohydrate BP

USP: United States Pharmacopoeia

BP: British Pharmacopoeia

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C, at a dry place. Protect from light.

Keep medicines out of reach of children.

6.5 Nature and contents of container

Each Carton contains 30ml amber bottle with calibrated dropper. An insert is kept in the carton along with bottle.

7. Marketing Authorization Holder

MEYER ORGANICS PVT. LTD.

10 D, 2nd Phase, Peenya Industrial Area,
Bangalore 560058.India

8. Marketing Authorization Number

FDA/SD.255-112071

9. Date of First Authorization or Renewal

19/11/2025

10. Date of Revision of the Text

27/11/2025