

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

LACINIL DROPS (Simethicone, Dill Oil, Fennel Oil Oral Drops).

2. Qualitative and quantitative composition

Each ml contains:

Simethicone Emulsion USP equivalent to Simethicone ... 40 mg

Dill Oil BP ... 0.005 ml

Fennel Oil ... 0.0007 ml

Flavoured syrup base q.s.

Excipients q.s.

Excipients of known effect: Methyl Paraben BP 2.2 mg, Propyl Paraben BP 0.33 mg (parabens), Sucrose BP 300 mg and Sorbitol Solution 70% BP 124.67 mg per ml.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid Drops (Oral Drops).

Off-white coloured, homogeneous suspension with characteristic flavour.

4. Clinical particulars

4.1 Therapeutic indications

LACINIL DROPS is indicated for the relief of infant colic, griping pain and flatulence (anti-flatulent/anti-gas) in the paediatric population.

Simethicone acts in the stomach and intestines to change the surface tension of gas bubbles, enabling smaller bubbles to combine into larger bubbles, resulting in easier elimination of gas by belching or passing flatus. Dill Oil and Fennel Oil reduce spasm and increase intestinal motility.

4.2 Posology and method of administration

Posology

Infants under 2 years of age: 2.5 ml three times daily, after meals and at bedtime.

Children 2-12 years of age: 5 ml three times daily, after meals and at bedtime, or as directed by the physician.

Paediatric population

For paediatric use only. LACINIL DROPS is not indicated for use in adults.

Method of administration

Oral use. Shake well before use.

4.3 Contraindications

LACINIL DROPS is contraindicated in patients with known hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

LACINIL DROPS should be used with caution in patients with liver disease, kidney disease and severe illness.

Physicians and pharmacists should be consulted before use in patients already receiving other medication.

4.5 Interaction with other medicinal products and other forms of interaction

Levothyroxine: Simethicone may bind to Levothyroxine, and absorption of Levothyroxine may be impaired if the preparation is given concurrently to infants treated for thyroid disorders.

Lithium: Dill Oil may increase the elimination of Lithium.

4.6 Fertility, pregnancy and lactation

Use with caution during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not applicable. LACINIL DROPS is a paediatric-use-only formulation.

4.8 Undesirable effects

Simethicone does not have any serious side effects.

Frequency	Adverse reaction
Minor (common)	Nausea, mild diarrhoea, constipation.
Rare	Hypersensitivity reactions including rash, pruritis, facial oedema, tongue oedema and respiratory difficulty.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdose

No specific antidote is known. In the event of overdose, management should be symptomatic and supportive, with monitoring of the patient as clinically indicated.

Excessive belching may result from swallowing air; contributory factors such as rapid eating or drinking, chewing gum and smoking should be identified and managed where relevant. If a dose is missed, the next dose should be taken at the scheduled time; the dose should not be doubled to make up for a missed dose.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action

Excessive swallowing of air results in collection of gas in the intestine, which may result from rapid eating, breastfeeding (inhalation of air along with milk), excessive use of a pacifier (dummy), and finger sucking or crying. When the swallowed air is in the intestine, bubbles form, making it more difficult for gas to pass through the intestinal canal, resulting in abdominal distension and pain.

Simethicone is a surface-active substance that changes the surface tension of gas bubbles in the stomach and intestines, allowing them to coalesce. It thereby acts as an antifoaming agent, reducing surface tension and collapsing gas bubbles, relieving flatulence, abdominal distension and dyspepsia. Simethicone is chemically inert and exerts a purely physical action.

Dill Oil and Fennel Oil contain volatile oils that produce smooth muscle relaxation, an antispasmodic effect, and increase intestinal motility.

5.2 Pharmacokinetic properties

Simethicone is chemically inert and is not absorbed from the gastrointestinal tract; it is excreted unchanged in the faeces.

5.3 Preclinical safety data

No preclinical safety data available.

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Name of excipient	Specification
1	Simethicone Emulsion (equivalent to Simethicone)	USP
2	Dill Oil	BP
3	Fennel Oil	USP
4	Methyl Paraben BP	BP
5	Propyl Paraben BP	BP
6	Sodium Hydroxide BP	BP
7	Arrowell CRT / Arrow Gum super	IH
8	Xanthan Gum BP (Plain)	BP
9	Guar BP (Delca P-225)	BP
10	Sucrose BP	BP
11	Sorbitol Solution 70% BP	BP
12	Propylene Glycol BP	BP
13	Polysorbate 80 BP (Tween 80)	BP
14	Sodium Saccharin BP	BP
15	Purified Water IH	IH

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a cool, dry place below 25°C. Keep out of reach of children.

6.5 Nature and contents of container

20 ml amber PET bottles, each with a 1 ml plastic dropper, packed with a leaflet insert in a carton. 5 cartons are wrapped with PVC shrink film, and 5 such shrink packs are packed in a 5-ply printed corrugated box.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

LASO HEALTHCARE PVT LTD

No.34, Poothapedu Main Road, NSC Bose Nagar, Porur, Chennai, 600116, India.

8. Marketing authorisation number

H2025/CTD8636/16536

9. Date of first authorisation/renewal of the authorisation

1st September 2025

10. Date of revision of the text

26th August 2026