SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Finished Pharmaceutical Product

Proprietary Name

AVARIN

2. Qualitative and Quantitative Composition

Each soft gelatin capsule contains:
Simethicone 300mg
Alverine Citrate 60mg

3. Pharmaceutical Form

Soft gelatin capsules

White colour, oily suspension, filled in 10 minim, oblong, green, opaque soft gelatin shell capsule

4. Clinical Particulars

4.1 Therapeutic Indications

Symptomatic treatment of gastrointestinal disorders such as irritable syndrome that consists of abdominal discomfort (bloating, distension, fullness, pain and/or cramps)

4.2 Posology and method of administration

Adults: One capsule 1-3 times daily after meals or as directed by a physician.

Special population

Contraindicated in pregnancy and lactation

Use of pediatrics

Contraindicated in children under the age of 12 years

Method of Administration: Oral route

4.3 Contraindications

- Hypersensitivity to any components of the product.
- Patients with intestinal obstruction or paralytic ileus.
- Pregnancy & lactation, children under 12 years old.

4.4 Special Warnings and Precautions for Use

Should not recommend when administering to hypotensive patients

Special population

Contraindicated in pregnancy and lactation

Use of pediatrics

Contraindicated in children under the age of 12 years

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Use in pregnancy and lactation

Should not be administered to pregnant & lactating women.

Fertility

None

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable Effects

Allergic reactions, including anaphylaxis, have also occurred.

A. Summary of the safety Profile

Simethicone has an excellent safety profile due to its non-systemic nature. It is not absorbed from the gastrointestinal tract and is excreted unchanged in feces. Therefore, systemic side effects are rare to non-existent. In clinical use, simethicone is well tolerated across age groups, including infants, children, and the elderly.

B. Tabulated Summary of Adverse Reactions

System Organ Class (MedDRA)	Frequency Category	Adverse Reaction
Gastrointestinal disorders	Rare	Nausea, mild diarrhea, regurgitation
Immune system disorders	Very rare	Hypersensitivity reactions (rash, pruritus)
Skin and subcutaneous tissue disorders	Very rare	Urticaria, angioedema

C. Description of Selected Adverse Reactions Hypersensitivity Reactions:
Though extremely rare, hypersensitivity to simethicone has been reported in the form of skin rashes, pruritus, or urticaria. These events are non-severe and typically resolve upon discontinuation of the product.
Gastrointestinal Disturbances:
Some patients have reported mild diarrhea or nausea, though causality is often unclear due to the underlying gastrointestinal condition. These symptoms are transient and self-limiting.

D. Special population

Contraindicated in pregnancy and lactation

E. Use of pediatrics

Contraindicated in children under the age of 12 years

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

In case of overdosage, please consult your physician.

Special population

Contraindicated in pregnancy and lactation

Use of pediatrics

Contraindicated in children under the age of 12 years

5. Pharmacological properties

5.1 Pharmacodynamic Properties

Alverine citrate is a smooth muscle antispasmodic which is approximately 3 times as potent as papaverine and with a longer duration of action. It is neither an anticholinergic nor a derivative of atropine. Its direct spasmolytic action appears to be due to the local anesthetic properties of the drug. It has not found to block ganglionic or skeletal neuromuscular transmission, nor to significantly reduce gastric or pancreatic secretion.

The clinical use of simethicone is based on its antifoam properties. Silicone antifoams spread on the surface of aqueous liquids, forming a film of low surface tension and thus causing collapse of foam bubbles. Simethicone reportedly allows mucus-surrounded gas bubbles in the GI tract to coalesce and be expelled

Special population

Contraindicated in pregnancy and lactation

Use of pediatrics

Contraindicated in children under the age of 12 years

5.2 Pharmacokinetic Properties

Absorption

Simethicone is not absorbed from the gastrointestinal tract following oral administration and thus remains confined to the lumen, exerting its action locally. Alverine citrate, on the other hand, is rapidly absorbed after oral administration and undergoes extensive first-pass metabolism. It is quickly converted in the liver to its primary active metabolite, which contributes to its pharmacological activity. Peak plasma concentrations of this active metabolite are typically reached within 1 to 1.5 hours after dosing.

Distribution

Simethicone does not distribute systemically, as it is not absorbed. Alverine and its metabolites do enter systemic circulation, but the parent compound has a short plasma half-life of approximately 0.8 hours. The primary active metabolite is more persistent in plasma, with an average half-life of about 5.7 hours, suggesting moderate systemic distribution before elimination.

Elimination

Simethicone is excreted unchanged in the feces, as it is not absorbed or metabolized. Alverine and its metabolites are primarily eliminated via the kidneys. The high renal clearance of the metabolites indicates that elimination occurs through active renal secretion. The absence of significant accumulation suggests efficient clearance upon repeated dosing.

Linearity/non-linearity: Not Applicable

Special population

Contraindicated in pregnancy and lactation

Use of pediatrics

Contraindicated in children under the age of 12 years

5.3 Preclinical Safety Data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Aerosil 200, Gelatin lime bovine 160 bloom (DGF), Glycerin, Purified water, Iron Oxide Yellow (E172), Iron Oxide Black (E172), Brilliant Blue (E 133), Titanium dioxide.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months from the date of manufacture

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and Contents of Container

Unit carton containing pvc/pvdc-aluminium blister packs of 3x10 and 5x10 capsule in a catch cover with literature insert. Not all packs may be marketed.

6.6 Special precaution for disposal and other handling

No special requirements.

7. Marketing Authorization Holder and Manufacturing Site

Addresses MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,
Samutprakarn 10280, Thailand.

8. Marketing Authorization Number

H2015/CTD3189/590

9. Date of first Registration/ Renewal of the Registration

17/12/2015

10. Date of revision of the text

July 2025, 12th August 2026