

**AVARIN**  
**(Simethicone 300 mg & Alverine Citrate 60 mg)**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT**

**AVARIN**

**1.1 Strength**

Alverine Citrate..... 60 mg

Simethicone.....300 mg

**1.2 Pharmaceutical form**

SOFT GEL CAPSULE

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**EACH SOFT GEL CAPSULE OF AVARIN CONTAINS**

Alverine Citrate..... 60 mg

Simethicone.....300 mg

For a full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

SOFT GEL CAPSULE

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic Indications**

Symptomatic treatment of gastrointestinal disorders such as irritable syndrome or irritable bowel syndrome or peptic ulcer and that consists of abdominal discomfort (bloating, distention, fullness, pain and/or cramps). It is also used in the treatment of dysmenorrhea

**4.2 Posology and method of administration**

Posology

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

**4.3 Method of administration**

Oral use

#### **4.4 Contraindications**

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

#### **4.5 Special warnings and precautions for use**

Should not recommend when administering to hypotensive patients.

#### **4.6 Paediatric population**

Not applicable

#### **4.7 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.8 Additional information on special populations**

None

#### **4.9 Paediatric population**

None

#### **4.10 Fertility, pregnancy and lactation**

Should not be administered to pregnant & lactating women.

#### **Fertility**

There are no data on the effects of alverine citrate or simeticone on human fertility.

#### **4.11 Effects on ability to drive and use machines**

None reported.

#### **4.12 Undesirable effects**

- Nausea, headache, pruritus, rash, dizziness and hypotension or temporary lowering of blood pressure have been reported.
- Allergic reactions, including anaphylaxis, have also occurred.

#### **4.13 Overdose**

In case of overdosage, please consult your physician.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### **Mechanism of Action of Alverine Citrate**

- Alverine citrate has been reported to exhibit a dual intestinal pharmacological activity.
- Alverine acts on vagal sensory endings of the GI tract, where it decreases the responses of mechanoreceptors to mechanical and chemical stimuli. Because chemically induced responses and smooth muscle contraction are both calcium dependent, decreased chemical sensitivity and smooth muscle relaxation can be explained by reduced calcium influx.

#### **Alverine exerts a spasmolytic effect on smooth muscle cells that acts through**

- Basal and stimulated motility via calcium-dependent and
- Independent inhibition of neuronal excitability, in addition, a calcium-independent mechanism of action, such as selective 5-HT<sub>1A</sub> receptor antagonism, might also be present.
- Alverine citrate has an anti-nociceptive effect associated with 5-HT<sub>1A</sub> receptor antagonism, allowing it to modulate nociceptive response and visceral hypersensitivity.
- Through smooth muscle cell L-type Ca<sup>2+</sup> channels.
- Alverine citrate should be considered a true spasmolytic, because it suppresses the duration of spontaneous contractions of the gut, preventing local ischemia and reflector pain in the colonic wall evoked by “spasms”.

#### **Mechanism of Action of Simethicone**

- Simethicone is an inert hydrophobic drug with an anti-foaming effect that acts to reduce flatulence.
- 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 allows the small bubbles of froth to coalesce into large bubbles, that can move easily be passed up from stomach or down from colon.
- Thus, gas is freed and eliminated more easily by belching or passing flatus.

### **5.2 Pharmacokinetic properties**

#### **Pharmacokinetics and Metabolism- Simethicone**

- Simethicone is physiologically inert: it does not appear to be absorbed following oral administration from the GI tract.
- It does not interfere with the absorption of nutrients or with gastric secretion.
- Following oral administration, the drug is excreted unchanged in faeces.

**Pharmacokinetics and Metabolism- Alverine citrate**

- Alverine citrate is absorbed from the gastrointestinal tract following oral administration and is rapidly metabolised to an active metabolite.
- The onset of action occurs within 30 to 60 minutes & continues for 3 to 4 hours.
- Peak plasma concentrations of which occur 1 to 1.5 hours after an oral dose.
- Further metabolism to inactive metabolites occurs; metabolites are excreted in the urine by active renal secretion.

**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

**6.4 Special precautions for storage**

Do not store above 30°C. Keep out of reach of children.

**6.5 Nature and contents of container**

Blister pack of 5 x 10s.

**6.6 Special precautions for disposal and other handling**

Any unused medicinal product or waste should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION 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 AUTHORISATION NUMBER:**

RWANDA: Rwanda FDA-HMP-MA-0601

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:**

RWANDA: 13/10/2023

**10. DATE OF REVISION OF THE TEXT**

06/11/ 2023