

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Simethicone-Asteria, 42 mg, chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 42 mg of simethicone.

Excipient(s) with known effect: each chewable tablet contains 435 mg of sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

White or slightly yellowish, round, slightly convex tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Functional treatment of symptoms associated with gas (abdominal distension, flatulence and meteorism).

Simethicone-Asteria chewable tablets are indicated in children aged 12 years or older and in adults.

4.2 Posology and method of administration

Posology

Simethicone-Asteria chewable tablets are indicated in children aged 12 years or older and in adults.

Children aged over 12 years:

1 or 2 tablets three to four times a day, after meals.

Do not use in children aged under 12 years.

Adults:

2 tablets, 4 times a day, after meals.

Due to the absence of intestinal absorption, there are no special precautions for the elderly, or in cases of kidney or liver failure.

Method of administration

Oral route.

The tablets should be chewed.

The duration of treatment should not exceed 10 days.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The tablets should be chewed and not swallowed whole.

Simethicone-Asteria chewable tablets are not indicated in children aged under twelve years due to the limited safety information.

Simethicone-Asteria chewable tablets contain sucrose (see section 6.1). Patients with rare hereditary problems of fructose intolerance, malabsorption of glucose-galactose or sucrose-isomaltose insufficiency should not take this medicine.

If the symptoms persist or worsen or in the case of prolonged obstipation, the patient should seek medical advice.

Do not use in if perforation or ileus is suspected.

4.5 Interaction with other medicinal products and other forms of interaction

Simethicone-Asteria may alter the bioavailability of other medicinal products that are being taken at the same time.

The simultaneous use of Simethicone-Asteria with laxatives based on mineral oils (paraffin) is not recommended, as the combination of these two medicinal products will reduce its efficacy.

4.6 Fertility, pregnancy and lactation

Pregnancy:

For simethicone, there are no clinical data on exposure of pregnant women.

Studies in animals about pregnancy, embryo-foetal development, childbirth or postnatal development are insufficient. As simethicone is not absorbed in the gastrointestinal tract, the potential risk in risk human beings is very low. As there is no experience in the use of simethicone during pregnancy, SIMETHICONE-ASTERIA should not be administered unless clinically justifiable.

Breast-feeding

The excretion of simethicone in breast milk is unknown. However, as simethicone is not absorbed in the gastrointestinal tract, the potential risk is very low. Simethicone may be used during breast-feeding only when the risk-benefit ratio is favourable.

Fertility

The preclinical data obtained with dimeticones do not reveal special risks for human beings, see section 5.3.

4.7 Effects on ability to drive and use machines

Simethicone-Asteria has no or negligible effect on the ability to drive and use machines.

4.8 Undesirable effects

In view of the absence of intestinal absorption, the risk of undesirable effects with simethicone is limited. The incidence of adverse events in published clinical trials is low (1.6%, based on close to 2500 patients exposed), and are primarily gastrointestinal alterations (overall incidence of 1%).

The undesirable effects are classified according to the MedDRA convention, by system, organ, class and by frequency as follows:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1000$)

Very rare ($< 1/10,000$)

Unknown (cannot be estimated from the available data)

Gastrointestinal alterations:

Uncommon: diarrhoea abdominal pain, ileus, nausea and vomiting.

Immune system disorders:

Rare: hypersensitivity reactions, such as rash, itching, swelling of the face and tongue, and breathing difficulty were also reported.

Reporting of suspected adverse reactions

It is important to report suspected adverse reactions after authorisation of the medicinal product, as this enables continuous monitoring of the risk-benefit ratio of the medicinal product.

4.9 Overdose

No cases of overdose have been described.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 6.3.2.2.3 - Digestive system. Modifiers of gastrointestinal motility. Modifiers of intestinal motility. Antidiarrheals. Antiflatulents. ATC Code: A03AX13

Mechanism of action

Regardless of where they come from, gases accumulate in the stomach and intestine in the form of bubbles of gas produced by the low surface tension and high viscosity of the gastrointestinal content.

Simethicone is a chemically inert substance that acts by modifying the surface tension of the bubbles of gas, acting as an antifoaming agent.

Simethicone is not absorbed in the gastrointestinal tract nor metabolised, therefore, the potential risk to risk human beings is very low.

5.2 Pharmacokinetic properties

Absorption

Simethicone is not absorbed in the gastrointestinal tract nor metabolised.

Elimination

Simethicone is excreted in the faeces.

5.3 Preclinical safety data

The pre-clinical data obtained with Simethicone do not reveal special risks for human beings, according to conventional studies on safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, reproductive toxicity and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sucrose
- Povidone
- Anhydrous colloidal silica
- Magnesium stearate
- Vanillin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

PVC and aluminium blister with 10 chewable tablets.
Packs of 20, 60 and 100 chewable tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

ASTERIA LLC
72/3 Nairi Zaryan Street, Yerevan 0051, Republic of Armenia

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE

MARKETING AUTHORISATION

10. DATE OF REVISION OF THE TEXT