

PACKAGE LEAFLET: INFORMATION FOR THE USER

Simethicone-Asteria, 42 mg, chewable tablets **Simethicone**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Take this medicine exactly as described in this leaflet, or exactly as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you have any side effects, including possible side effects not listed in this leaflet, talk to your doctor, pharmacist, or nurse. See section 4.
- If you do not feel better or get worse, you must consult a doctor.

What is in this leaflet:

1. What Simethicone-Asteria is and what it is used for
2. What you need to know before taking Simethicone-Asteria
3. How to take Simethicone-Asteria
4. Possible side effects
5. How to store Simethicone-Asteria
6. Contents of the pack and other information

1. What Simethicone-Asteria is and what it is used for

Antiflatulent.

Simethicone-Asteria contains simethicone as active substance. Simethicone belongs to a group of medicines that reduce the accumulation of gas in the stomach and intestines.

Children aged 12 years or older and Adults

Simethicone-Asteria is used to treat functional abdominal distension, flatulence and meteorism (symptoms related to the accumulation of gas).

If you do not feel better or get worse, you must consult a doctor.

2. What you need to know before taking Simethicone-Asteria

Do not take Simethicone-Asteria

- if you are allergic to simethicone or any other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Simethicone-Asteria

If you have difficulty in chewing tablets.

Simethicone-Asteria chewable tablets should not be used in the case of suspected intestinal obstruction (ileus).

Children

Simethicone-Asteria chewable tablets are not recommended in children aged under 12 years due to the limited safety information.

Other medicines and Simethicone-Asteria

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Simethicone-Asteria should not be used together with liquid paraffin, a laxative which is a mineral oil.

Simethicone-Asteria with food or drinks

No effect.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:

There are no data on the use of simethicone in pregnancy. However, as simethicone is not absorbed in the stomach or intestines, the potential risk is very low. As there are no data on its use during pregnancy, talk to your doctor before taking Simethicone-Asteria.

Breast-feeding:

The passing of simethicone into breast milk is unknown. However, as simethicone is not absorbed in the stomach or intestines, the potential risk is very low. Ask your doctor for advice before taking any medicine.

Driving and using machines

No effect.

Simethicone-Asteria contains sucrose.

Patients who are diabetic or under sugar reduction regimes should take into account that Simethicone-Asteria contains sucrose (435 mg per chewable tablet).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Simethicone-Asteria

Take this medicine exactly as described in this leaflet, or exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for children aged 12 years or older is 1 or 2 tablets, 3 to 4 times a day, and for adults it is 2 tablets, 4 times a day. The tablets should be chewed and taken after meals.

The duration of treatment should not exceed 10 days.

Use in children

Simethicone-Asteria chewable tablets are not recommended in children aged under 12 years due to the limited safety information.

Talk to your doctor or pharmacist if you feel that the effect of Simethicone-Asteria is very strong or very weak.

If you take more Simethicone-Asteria than you should
Talk to your doctor or pharmacist about what to do.

If you forget to take Simethicone-Asteria:
Do not take a double dose to make up for a forgotten dose.
Talk to your pharmacist about what to do.

If you stop taking Simethicone-Asteria
There are no effects of stopping the treatment with Simethicone-Asteria.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

As a result of taking this medicine, uncommon effects may occur such as diarrhoea and abdominal pain, intestinal obstruction (ileus) nausea and vomiting. Rare cases (at least 1 case in 10,000 patients) of hypersensitivity reactions, such as rash, itching, swelling of the face and tongue, and breathing difficulty have been reported.

If one or various of these symptoms appear, talk to your doctor or pharmacist about what to do. Never stop the treatment without first asking your doctor or pharmacist.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist.

Reporting of special adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the vigilance@pharm.am or Hot Line: (+374 10) 20-05-05, (+374 96) 22-05-05.

5. How to store Simethicone-Asteria

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use this medicine if you notice any signs of deterioration of the blister.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Simethicone-Asteria contains

- The active substance is simethicone. Each chewable tablet contains 42 mg of simethicone.
- The other components are: sucrose, povidone, anhydrous colloidal silica, magnesium stearate and vanillin.

What Simethicone-Asteria looks like and contents of the pack:

Simethicone-Asteria is a white or slightly yellowish, round, slightly convex tablet.

Packs of 20, 60 or 100 chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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