

Technical Documentation in accordance with Medical Device Regulation (EU) 2017/745
Simeticone 125 mg granules

Sachet

<trade name>

125 mg simethicone use without water



Manufacturer:

Fairpharm Vertriebs GmbH
Georg-Kalb-Straße 5
82049 Pullach i. Isartal
Germany
www.fairpharm.com



Distributor:

company name, address, website with product information



<Expiry date>



<Batch number>



Medical Device



Please read instructions for use!

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Simeticone 125 mg granules

Carton box

<trade name>

Granules containing 125 mg of simeticone

For oral use without water

<x> sachets

Against gas related intestinal conditions such as bloating, feeling of fullness, cramp-like pain in the abdomen.

Composition:

1 sachet contains: 125 mg of simeticone

Other ingredients: lemon flavour, malic acid, cream flavour, sorbitol, talc.

Contains Sorbitol!

With increased gas formation in the gastrointestinal tract, bloating, feeling of fullness and cramp-like abdominal pain can occur.

<Trade name> helps to remove the annoying air in the stomach and so relieves the symptoms.

Suited for diabetics. 1 sachet contains 0.05 carbohydrate units.

Keep out of reach of children.



Please read instructions for use!



UDI



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Instructions for use

<trade name>



Dear customer!

With <trade name> you have chosen a product that will help you quickly and reliably with gas-related gastrointestinal complaints. It is very well tolerated.

Please read the entire instructions for use carefully because they contain important information for you.

This medical device is available without prescription. In order to achieve the best possible treatment success, <trade name> should be used according to the instructions as described below.

Keep these instructions for use. You might want to read them again. Your doctor or pharmacist will also advise you.

If your symptoms worsen or do not improve, you should see a doctor.

These instructions for use contain:

1. What is <trade name> and what is it used for?
2. What should you observe before you take <trade name>?
3. How to take <trade name>
4. What are possible side effects?
5. How to store <trade name>
6. Further information

1. What is <trade name> and what is it used for?

This medical device contains simeticone, a substance with defoaming properties.

<Trade name> is used

- to relieve and treat symptomatic gas related conditions such as bloating (meteorism), feeling of fullness, cramp-like abdominal pain, pain in the upper abdomen, belching and functional dyspepsia.
- for preparation of diagnostics in the abdomen, such as endoscopy, x-ray and sonography.

2. What should you observe before you take <trade name>?

Do not use <trade name> if you are hypersensitive (allergic) to simeticone or any of the other ingredients of <trade name>.

In the event of new and/or prolonged abdominal discomfort, you should consult a doctor so that the cause of the discomfort and a possibly underlying disease requiring treatment can be identified.

Pregnancy and breast-feeding

<trade name> can be used without reservations during pregnancy and when breast-feeding, as it is excreted from the intestines unchanged and is not taken up by the body. However, it is recommended to consult a doctor before use.

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Use in children

For children under 6 years other dosage forms are recommended.

Use in diabetics

<Trade name> can be used by diabetics. The granules are sugar-free.

Each sachet contains 0.05 carbohydrate units (1 carbohydrate unit being equal to 12 g of digestible carbohydrates).

Important information about certain other substances of <trade name>

This medical device contains sorbitol. Please consult your doctor before taking <trade name> if you know that you are intolerant to some sugars.

Interactions of <trade name> with other agents

None known to date.

3. How to take <trade name>

Always take <trade name> according to these instructions for use. You should check with your doctor or pharmacist if you are not sure.

Dosing and duration of use

The following information applies unless your doctor has prescribed <trade name> to you otherwise.

For gas related intestinal conditions:

Adults and adolescents 14 years and above take the contents of 1 sachet each before or after meals. If required, the contents of 1 sachet can also be taken before going to bed. Take the granules directly in the mouth on the tongue and swallow them. You may drink some water afterwards if you wish. The dose can be increased up to 2 sachets each, if required. The daily dose should not exceed 8 sachets, equivalent to 1,000 mg of simeticone.

Children from 6 - 14 years take the contents of 1 sachet each before or after meals directly in the mouth on the tongue and swallow them. You may drink some water afterwards if you wish. If required, the contents of 1 sachet can also be taken before going to bed. The daily dose should not exceed 3 sachets, equivalent to 375 mg of simeticone.

Age	Single dose	Maximum daily dose
Adults and adolescents 14 years and above	1 – 2 sachets (equivalent to 125 mg to 250 mg of simeticone)	8 sachets (equivalent to 1000 mg of simeticone)
Children from 6 to 14 years	1 sachet (equivalent to 125 mg of simeticone)	3 sachets (equivalent to 375 mg of simethicone)

<trade name> is suitable for long term use. It may be used until complaints improve. If you forgot to take <trade name>, just continue to use it without changing the dose. You must contact a doctor if your symptoms worsen or do not improve.

For preparation of imaging diagnostics:

Adults, adolescents and children from 6 years on take on the day before the examination the contents of 2 to 3 sachets and in the morning of the day of the examination the contents of 1 sachet. Take the granules directly in the mouth on the tongue and swallow them. You may drink some water afterwards if you wish.

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Age	On the day before the examination	In the morning of the day of the examination
Adults, adolescents and children from 6 years on	2 - 3 sachets (equivalent to 250 mg to 375 mg of simeticone)	1 sachet (equivalent to 125 mg of simeticone)

What to do if you took more <trade name> than you should?

Even large quantities are well tolerated, since the active substance of the granules acts only physically and is biologically and chemically completely inactive.

What happens if you stop taking <trade name> prematurely?

In this case the symptoms may reappear.

4. What are possible side effects?

Simeticone acts purely physically and is not absorbed from the gastro-intestinal tract. Therefore, side effects of simeticone are not expected.

However, if you notice any side effects, please inform your doctor or pharmacist.

You should report any serious incident that has occurred in relation to this product to the manufacturer and to *contact details of the competent authority in the country where the product is distributed*.

5. How to store <trade name>

Keep out of the reach and sight of children.

Do not use <trade name> after the expiry date which is printed on the carton and sachet.

6. Further Information

If severe bloating does not lessen after about one week, a doctor should be visited. Flatulence and a feeling of bloating when the stomach is empty are also a reason to consult a doctor. It is also advisable to see a doctor when the consistency of the stool changes, the bloating is very painful, or there are other symptoms in addition to bloating.

Each sachet contains 125 mg of simeticone.

Other ingredients: lemon flavour, malic acid, cream flavour, sorbitol, talc.

<trade name> is available in packs of <x> and <y> sachets.



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Last revised: September 2025

Additional consumer information:

What causes flatulence?

Discomfort caused by gas accumulation in the gastro-intestinal tract (flatulence) is a common symptom in modern life and can have different causes often related to our lifestyle:

Swallowing air. When we eat and drink, a certain amount of air is swallowed. This amount is increased if food is eaten too fast without being chewed properly.

Stress. In stressful situations, stress hormones make our body concentrate on more important functions to increase the capacity of muscles and nerves. This often happens at the cost of the digestion.

Wrong diet. Eating too much fatty or sugar-containing food, as well as drinking fizzy drinks and smoking. But some healthy food also tends to cause gas, for example cabbage, legumes, onions, grapes, asparagus or fresh bread.

Lack of exercise. Movement has a positive effect on our digestive tract and is therefore helpful against flatulence.

How does *<trade name>* work?

<trade name> for flatulence contains the tried and tested active substance simeticone. It disintegrates the many stubborn foam bubbles that are responsible in the intestines for flatulence. The foam decomposes; the gas escapes and can be broken down in natural ways. *<trade name>* helps with a purely physical mode of action.