

Simeticone 250 mg granules

Sachet

<Trade name>

250 mg Simeticone



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!

Simeticone 250 mg granules

Carton box

Only one sachet per dose!

<Trade name>

250 mg Simeticone

<x> sachets

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

Highly dosed

Only 1 sachet per dose

Oral use without water

Tastes pleasantly of lemon

Also ideal for on the go

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

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

For adolescents and adults

Composition: 1 sachet contains: 250 mg simeticone. Other ingredients: lemon flavour, malic acid, cream flavour, sorbitol, talc.

Contains Sorbitol!

Suited for diabetics. 1 sachet contains 0.1 carbohydrate units

Keep out of reach of children.



Please read instructions for use!



UDI



batch number:



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Simeticone 250 mg granules



Medical Device

Simeticone 250 mg granules

Instructions for use

<Trade name>
250 mg simeticone
Micro Granules



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 it contains important information for you.

In order to achieve the best possible treatment success, *<trade name>* should be used according to the instructions as described below.

Keep the instructions for use. You might want to read it 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 *<trade name>* is and what it is used for
2. Before you take *<trade name>*
3. How to take *<trade name>*
4. Possible side effects
5. How to store *<trade name>*
6. Further information

1. What *<trade name>* is and what it is 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, cramping abdominal pain, pain in the upper abdomen, eructation and functional dyspepsia.
- for preparation of diagnostics in the abdomen, such as endoscopy, x-ray and sonography.

2. 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.

Simeticone 250 mg granules

Use in children

For children under 14 years other dosage forms are recommended.

Use in diabetics

<Trade name> can be used by diabetics. The granulate is sugar-free.

Each sachet contains 0.1 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.

Does <trade name> have any interactions 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.

How to dose

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 daily dose should not exceed 4 sachets, equivalent to 1,000 mg of simeticone.

Age	Single dose	Daily dose
Adults and adolescents above 14 years	1 sachet (equivalent to 250 mg simeticone)	4 sachets (equivalent to 1000 mg simeticone)

<Trade name> is suited for long term use. It is taken until the symptoms improve. It is advisable to seek the advice of a doctor. 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:

Age	On the day before the examination	In the morning of the day of the examination
Adults and adolescents above 14 years	1 - 2 sachets (equivalent to 250 mg to 500 mg simeticone)	1 sachet (equivalent to 250 mg 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.

Simeticone 250 mg granules

What to do if you forgot to take *<trade name>*?

Continue treatment without changing the dose.

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

In this case, the symptoms may recur.

4. Possible side effects

No side effects have been observed in connection with the use of *<trade name>*.

The active ingredient simeticone dissolves the foam in the stomach and intestines and is not resorbed from the gastrointestinal tract. Therefore, no side effects from simeticone are expected even with large quantities.

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 this product out of the reach and sight of children.

Do not use 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 250 mg of simeticone.

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

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



Medical Device



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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.