

PACKAGE LEAFLET: INFORMATION FOR THE USER***Espumisan 100 mg/ml oral drops, emulsion***

100 mg/ml, oral drops, emulsion

Active substance: simeticone

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use *Espumisan comfort* carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if the symptoms worsen or do not improve.
- If you notice a side effect, please tell your doctor or pharmacist.

In this leaflet:

1. What *Espumisan 100 mg/ml oral drops, emulsion* is and what it is used for
2. Before you use *Espumisan 100 mg/ml oral drops, emulsion*
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1. What *Espumisan 100 mg/ml oral drops, emulsion* is and what it is used for

Espumisan 100 mg/ml oral drops, emulsion treats the symptoms of flatulence (wind and trapped wind) and is suitable for all age-groups. It works by disintegrating gas bubbles embedded in the food mass and in the mucus of the digestive tract. The gases released in the process can then be taken up by the intestinal wall, as well as removed by intestinal movement.

Uses

Espumisan 100 mg/ml oral drops, emulsion is used:

- for treating the symptoms of gas-related gastro-intestinal complaints, for example build up of gas in the intestines (meteorism), flatulence or when there is an increase in intestinal gas after operations;
- for preparing diagnostic procedures in the abdominal region (e.g. X-ray and sonography, endoscopic examinations, as an adjunct to contrast media suspensions).

2. Before you use *Espumisan 100 mg/ml oral drops, emulsion*

Do not use *Espumisan 100 mg/ml oral drops, emulsion*:

- if you are allergic (hypersensitiv) to the active substance simeticone or any of the other ingredients of *Espumisan 100 mg/ml oral drops, emulsion*. Please keep in mind when administering *Espumisan 100 mg/ml oral drops, emulsion* to others that this may also apply to them.

Take special care with *Espumisan 100 mg/ml oral drops, emulsion*

In both new and/or persistent stomach complaints you should visit a doctor. They will investigate whether there is an underlying disease that requires other treatment.

Particularly if used in infants and children, the doctor should be consulted.

Taking other medicines

Interactions with other medicines are not known.

Taking *Espumisan 100 mg/ml oral drops, emulsion* with food and drink

No special features are to be noted.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Since no clinical data on exposed pregnancies are available, the use of *Espumisan 100 mg/ml oral drops, emulsion* during pregnancy and breast-feeding is not recommended.

Driving and using machines

No special precautions are required.

Important information about some of the ingredients of *Espumisan 100 mg/ml oral drops, emulsion*

This medicinal product contains sorbitol. If you have been told by your doctor that an intolerance to some sugars exists, contact your doctor before using this medicinal product.

3. How to use *Espumisan 100 mg/ml oral drops, emulsion*

Always use *Espumisan 100 mg/ml oral drops, emulsion* exactly according to the instructions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

There are two ways to measure a dose of *Espumisan 100 mg/ml oral drops, emulsion*:

Depending on how high the dose is, dosing can take place with:

- a dropper insert,
- a measuring cap with millilitre (ml) graduation.

More detailed instructions on using the measuring devices can be found after the dose tables.

Dosage

Dose *Espumisan 100 mg/ml oral drops, emulsion* according to the intensity of the complaints.

The usual dose is:

For treating the symptoms of gas-related gastro-intestinal complaints

Age-group	Dosage in drops (dropper insert)
Infants	5 -10 drops each are put into the bottle feed or administered to the infant with a small spoon immediately before every breast-feeding
1 - 6 years	10 drops 3 to 5 times daily
6 - 14 years	10 - 20 drops 3 to 5 times daily
Adolescents and adults	20 drops 3 to 5 times daily

It is also possible to take *Espumisan 100 mg/ml oral drops, emulsion* after operations.

Espumisan 100 mg/ml oral drops, emulsion is taken with or after meals, also before going to bed if necessary.

Espumisan 100 mg/ml oral drops, emulsion should be taken for as long as the complaints persist.

Espumisan 100 mg/ml oral drops, emulsion is suitable to be taken over a long period of time only upon medical advice. Please also read Section 2 "Take special care".

For preparing diagnostic procedures

Dosage in ml (measuring cap)
1 ml 3 times daily after meals on the day before the examination and 1 ml on the morning of the examination

As an adjunct to contrast media suspensions

Dosage in ml (measuring cap)
2 - 4 ml to 1 litre of contrast meal for

double-contrast imaging

For preparing inspections of the stomach and small intestine (endoscopy)

Dosage in ml (measuring cap)
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2 - 3 ml before endoscopy

If necessary, a few more ml of the emulsion can be put through the instrument canal of the endoscope during the examination to eliminate interfering foam bubbles.
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Method of use

Shake well before use!

Using the dropper insert (10 - 25 drops):

The bottle must be held vertically with the dropper insert facing downwards.

25 drops are equivalent to 1 ml of the emulsion (equivalent to 100 mg simeticone).

Using the measuring cap:

As a measuring device, a measuring cap with ml graduation is attached to the screw-cap of the 30-ml and 50-ml dropper bottles. If necessary (for example with doses of 25 drops and more), it can be pulled off and used instead of the dropper insert to measure off the dose.

Note: Due to the danger of swallowing, the measuring cap should be kept away from children.

If you use more *Espumisan 100 mg/ml oral drops, emulsion* than you should

Taking too much *Espumisan 100 mg/ml oral drops, emulsion* is unlikely to cause any ill effect. Even large quantities of *Espumisan 100 mg/ml oral drops, emulsion* are tolerated without causing problems. The active substance of *Espumisan 100 mg/ml oral drops, emulsion*, simeticone, makes foam in the gastro-intestinal canal disintegrate in a purely physical way. Simeticone is not absorbed and not changed chemically or enzymatically during passage through the intestines.

If you forget to use *Espumisan 100 mg/ml oral drops, emulsion*

You can make up for the dose at any time.

If you stop using *Espumisan 100 mg/ml oral drops, emulsion*

There may be a recurrence of the complaints.

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

4. Possible side effects

To date, *Espumisan 100 mg/ml oral drops, emulsion* has not been associated with any side effects.

If you notice any side effects, please tell your doctor or pharmacist.

5. How to store *Espumisan 100 mg/ml oral drops, emulsion*

No special storage conditions are required for this medicine.

Keep out of the reach and sight of children.

Do not use *Espumisan 100 mg/ml oral drops, emulsion* after the expiry date which is stated on the outer carton and label after "EXP". The expiry date refers to the last day of that month.

Espumisan 100 mg/ml oral drops, emulsion can be used for up to 6 months after first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information**What *Espumisan 100 mg/ml oral drops, emulsion* contains**

The active substance is simeticone.

1 ml of oral emulsion contains 100 mg simeticone.

The other ingredients are:

Macrogol stearate, glycerol monostearate 40-55, sorbic acid, sodium hydroxide for pH adjustment, acesulfame potassium, sodium chloride, liquid sorbitol (non-crystallising) (E 420), carbomer, sodium citrate, banana flavour, purified water

What *Espumisan 100 mg/ml oral drops, emulsion* looks like and contents of the pack

Espumisan 100 mg/ml oral drops, emulsion is a milky-white, slightly viscous emulsion in a labelled 30-ml or 50-ml amber-glass bottle with dropper insert, screw-cap and attached measuring cap.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

BERLIN-CHEMIE AG
(Menarini Group)
Glienicke Weg 125
12489 Berlin, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom (RMS)	Espumisan 100 mg/ml oral drops, emulsion
Bulgaria	Еспумизан комфорт 100 mg/ml перорални капки, емулсия
Czech Republic	Espumisan kapky 100 mg/ml
Estonia	Espumisan 100 mg/ml
Finland	Espumisan 100mg/ml tipat, emulsio
Hungary	Espumisan 100 mg/ml belsőleges emulzió
Latvia	Espumisan 100 mg/ml emulsija iekšējai lietošanai
Poland	Espumisan 100 mg/ml
Romania	Espumisan 100 mg/ml, picături orale, emulsie
Slovenia	Espumisan 100 mg/ml, peroralne kapljice, emulzija
Slovak Republic	Espumisan comfort 100 mg/ml perorálne emulzné kvapky

This leaflet was last revised in 12/2013.