

Package leaflet: information for the user

Espumisan L 40 mg/mL oral drops, emulsion simeticone

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Espumisan L is and what it is used for
2. What you need to know before you use Espumisan L
3. How to use Espumisan L
4. Possible side effects
5. How to store Espumisan L
6. Contents of the pack and other information

1. What Espumisan L is and what it is used for

Espumisan L belongs to a group of medicines called gastrointestinal medicines. Its active substance simeticone breaks up gas bubbles in the food mass and intestinal mucous. The released gas is later absorbed by the intestinal walls and extracted with bowel movements.

- Used for gastrointestinal complaints associated with gas accumulation, the symptom of which is flatulence.
- As a supplementary agent for preparation for gastrointestinal tract diagnostic investigations (e.g. X-ray, ultrasound or gastroscopic investigations).
- As an ancillary preparation to reduce foam in the gastrointestinal tract after accidental ingestion of washing agents.

2. What you need to know before you use Espumisan L

Do not use Espumisan L

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Espumisan L.

The complaints caused by gas accumulation may also be symptoms of other, more serious disease of gastrointestinal tract.

If symptoms like:

- feeling of tension and fullness;
- emergence of gas from mouth;
- “rumbling” of abdomen;
- gastric distension (due to excess gas)

occur or persist, contact your doctor. The doctor examines the cause of the complaints excluding the presence of disease that would require other treatment.

Other medicines and Espumisan L

Interactions of Espumisan L with other medicines have not been observed so far.

Pregnancy, breast-feeding and fertility

There are no restrictions to using Espumisan L when pregnant or breast-feeding.

Driving and using machines

No special instructions.

Espumisan L contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per mL, that is to say essentially 'sodium-free'.

3. How to use Espumisan L

Always use Espumisan L exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Usage

Shake the bottle before use. Hold the bottle upside down to use the dropper. 25 drops (1 mL of oral emulsion) contains 40 mg of simeticone.

Posology

Treatment of symptoms related to gastrointestinal gas.

For example, flatulence

| Age | Dose in drops (ml) | Frequency of use |
|--|---------------------------------------|--|
| Infants | 25 drops (equivalent to 1 mL) | into feeding bottle during each meal or administer to the child before or after nursing. |
| Children 1...6 years old | 25 drops (equivalent to 1 mL) | 3...5 times a day |
| Children 6...14 years old | 25 to 50 drops (equivalent to 1-2 mL) | 3...5 times a day |
| Adolescents over 14 years old and adults | 50 drops (equivalent to 2 mL) | 3...5 times a day |

Note: Espumisan L may be used also post-operatively.

Espumisan L is taken during or after meal, also before going to sleep if required. The duration of treatment is determined by the course of the complaints. Espumisan L may be used for longer time if required. If the complaints persist, see section 2, "Warnings and Precautions".

For preparation for diagnostic investigations of the gastrointestinal tract:

X-ray and ultrasound investigations

| Day before investigation | Morning of the investigation day |
|--|----------------------------------|
| 50 drops (corresponds to 2 mL) 3 times a day | 50 drops (corresponds to 2 mL) |

As a supplement to contrast agent suspension (for diagnostic investigations of the gastrointestinal tract):

100...200 drops (corresponds to 4...8 mL) of Espumisan L to be added to 1 litre of oral contrast agent for radiography.

As an antidote for poisoning with washing agents:

Depending on the severity of poisoning.

| Age | Dose |
|----------|--|
| Children | 65 drops to 1/3 of the bottle (corresponds to 2.5...10 mL) of Espumisan L. |
| Adults | 1/3...2/3 of the bottle (corresponds to 10...20 mL) of Espumisan L. |

Attention!

If you use Espumisan L as a first aid agent after intake of washing agent, the doctor should be contacted **immediately!**

If you feel that the effect of Espumisan L is too strong or too weak, talk to your doctor or pharmacist.

If you use more Espumisan L than you should

There are no known cases of Espumisan L toxicosis.

The active substance of Espumisan L, simeticone, breaks up the foam in the gastrointestinal tract physically and is completely biologically and chemically inactive. This means toxicity is practically impossible. Even large doses of Espumisan L are tolerated very well.

If you forget to use Espumisan L

You can take the next dose at any time convenient for you.

If you stop using Espumisan L

The symptoms may recur after the use of Espumisan L is stopped.

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

4. Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Espumisan L

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

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

A note about the stability of this medicine after it is first opened:

After first opening of the bottle Espumisan L is usable for 6 months.

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 Espumisan L contains

- The active substance is simeticone. 25 drops (1 mL of oral emulsion) contains 40 mg of simeticone.
- The other excipients are: macrogol stearate, glycerol monostearate 40-55, sorbic acid, sodium hydroxide, sodium chloride, carbomers, sodium citrate, sucralose, purified water.

What Espumisan L looks like and contents of the pack

Milky white to yellow low-viscous emulsion.

Espumisan L is supplied in a 30 ml amber glass bottle with a polypropylene cap with a flip-off ring and a polypropylene dropper, which can be opened.

1 or 3 bottles in carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

BERLIN-CHEMIE AG

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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