

PACKAGE LEAFLET: INFORMATION FOR THE USER

ESPUMISAN

40 mg soft capsules

SIMETHICONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What ESPUMISAN is and what it is used for
2. Before you take ESPUMISAN
3. How to take ESPUMISAN
4. Possible side effects
5. How to store ESPUMISAN
6. Further information

1. WHAT ESPUMISAN IS AND WHAT IS IT USED FOR

ESPUMISAN capsules contain simethicone, a substance that leads to the dissolution of gas bubbles. 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:

- 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 a feeling of fullness;
- for preparing diagnostic procedures in the abdominal region (e.g. X-ray and sonography, endoscopic examinations, as an adjunct to contrast media suspensions).

Be sure to consult a doctor if you do not feel better or if you feel worse.

They are intended for children above 6 years, adolescents and adults.

2. BEFORE YOU TAKE ESPUMISAN

Do not take ESPUMISAN

If you are allergic to:

- simethicone
- color sunset yellow FCF (E 110)
- methyl (E 218)
- some of the other ingredients of this medicine (listed in section 6)

Take special care with ESPUMISAN

Problems caused by the formation of gas can be a sign of serious problems with the stomach or intestines.

Symptoms may include:

- feeling of pressure and fullness
- belching
- rumbling in the intestines
- flatulence.

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.

Taking other medicines

Interactions with other medicines are not known.

Taking Espumisan 40 mg soft capsule 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.

As simethicone is excreted in the unchanged form from the intestines and it is not absorbed into the body, it can be taken without restrictions during pregnancy and breastfeeding. However, it is advisable to consult a doctor before taking this medicine.

3. HOW TO TAKE ESPUMISAN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Method of use

Shake well before use!

The bottle must be held vertically with the dropper insert facing downwards. 25 drops are equivalent to 1 ml of the emulsion (equivalent to 40 mg of simeticone).

Dosage

For treating the symptoms of gas-related gastro-intestinal complaints, build up of gas in the intestines (meteorism), flatulence

Age group	Dosage	Frequency
Children over 6 years age, adolescents and adults (simethicone)	2 capsules (Corresponding to 80 mg of simethicone)	3 to 4 times a day

It is also possible to take Espumisan 40 mg soft capsule after operations.

Espumisan 40 mg soft capsule is taken with or after meals, also before going to bed if necessary. Espumisan 40 mg soft capsule should be taken for as long as the complaints persist. Espumisan 40 mg soft capsule is suitable to be taken over a long period of time only upon medical advice. Please also read Section 2 "Take special care".

As a preparation for diagnostic tests in the area of the stomach and intestines,

- radiological and ultrasound examination:

On the day before the examination
2 capsules 3 times a day

On the morning of the examination
2 capsules

(Corresponding to a total amount
of 240 mg of simethicone)

(Corresponding to 80 mg of simethicone)

You must contact a doctor if your symptoms get worse or do not improve.

If you take more ESPUMISAN than you should

Taking too much Espumisan is unlikely to cause any ill effect. Even large quantities of Espumisan are tolerated without causing problems. The active substance simeticone makes foam in the gastro-intestinal canal disintegrate in a purely physical way. Simeticone is not absorbed into bloodstream.

If you forget to take ESPUMISAN

You can make up for the dose at any time.

If you stop taking ESPUMISAN

After you stop taking ESPUMISAN, the problems can occur again.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

To date, it has not been associated with any side effects.

Espumisan 40 mg soft capsules contain color sunset yellow FCF (E110) which may cause allergic reactions.

Espumisan 40 mg soft capsules contain preservative methylhydroxybenzoate (E218) which may cause allergic reactions that can be delayed.

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

5. HOW TO STORE ESPUMISAN

Keep out of the reach and sight of children.

Do not use **ESPUMISAN** after the expiry date which is stated on the label.

Store below 30 C.

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 contains

The active ingredient is simethicone.

One Espumisan 40 mg soft capsule contains 40 mg of simethicone.

The other ingredients are:

methylhydroxybenzoate (E 218) [Ph. Eur.], Gelatin, glycerin (85 percent), color Quinoline yellow (E 104); color sunset yellow FCF (E 110).

What ESPUMISAN looks like and contents of the pack

Espumisan 40 mg capsules are almost round, yellow soft gelatin capsule with a smooth surface, with a visible line at the joint.

The contents of the capsule is colorless and can be slightly blurred.

Espumisan 40 mg soft capsules are available in packages of 25, 50 and 100 soft capsules.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

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