

## ESPUMISAN EASY

125 mg Granules

SIMETHICONE

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*• 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 •*

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### What is in this leaflet?

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

#### *1. WHAT ESPUMISAN EASY IS AND WHAT IS IT USED FOR*

ESPUMISAN EASY granules contain simethicone, a substance that leads to the dissolution of gas bubbles. ESPUMISAN EASY is used to effectively relieve flatulence caused by accumulations of gas and to reduce feelings of tension in the abdomen, bloating, pressure in the upper abdomen and rumbling in the stomach and intestines.

ESPUMISAN EASY quickly dissolves in the mouth, making the active substance rapidly reach the gastrointestinal tract, where it acts. ESPUMISAN EASY is presented in single sachets that you can carry with you at any time to relieve unpleasant symptoms of flatulence or other gas-related conditions. The granules do not need to be taken with water and have a pleasant lemon taste.

#### *2. BEFORE YOU TAKE ESPUMISAN EASY*

##### **Do not take ESPUMISAN EASY**

- If you are allergic (hypersensitive) to simethicone or any other ingredient of Espumisana Easy.

##### **Take special care with ESPUMISAN EASY**

### ***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.

### ***Use in children***

ESPUMISAN EASY is not suitable for children under 6 years of age.

### ***Use in diabetics***

ESPUMISAN EASY does not contain sugar and can be taken by diabetics.

One bag = 0,05 bread units (1 unit of bread corresponds to 12 g of digestible carbohydrates).

### ***Other warnings***

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

## **3. HOW TO TAKE ESPUMISAN EASY**

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.

### ***Dosage***

Adults and adolescents older than 14 years

Take the contents of one bag before or after each meal. If necessary, the contents of one bag can be taken before going to sleep.

The dose may, if necessary, be increased to 2 bags taken with a meal.

The daily dosage should not exceed 8 bags, which is equivalent to 1000 mg of simethicone.

### ***Children from 6 to 14 years***

Take the contents of one bag before or after a meal. If necessary, the contents of one bag can be taken before going to sleep.

The daily dose should not exceed 3 bags, corresponding to 375 mg of simethicone.

### ***Method of administration***

Pour the granules directly on the tongue and swallow. If you want, you can drink water afterwards.

Do not take ESPUMISAN EASY for more than 30 days. You must contact a doctor if your symptoms get worse or do not improve.

### ***If you take more ESPUMISAN EASY 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 and not changed chemically or enzymatically during passage through the intestines.

### ***If you forget to take ESPUMISAN EASY***

You can make up for the dose at any time.

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.

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

## 5. HOW TO STORE ESPUMISAN EASY

Keep out of the reach and sight of children.

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

## 6. FURTHER INFORMATION

### **What ESPUMISAN EASY contains**

**If severe bloating does not decrease after about one week, you should see a doctor.**

**Flatulence and bloating with an empty stomach are also reasons for consulting a doctor. It is recommended to contact your doctor if the consistency of stools change, if bloating is very painful or if there are other symptoms with flatulence.**

One bag contains 125 mg of simethicone.

Other ingredients: sorbitol, talc, malic acid, lemon flavor, cream flavor

### **What ESPUMISAN EASY looks like and contents of the pack**

One bag contains 0.8 granules. 28 bags in a box.

### **Regime of dispensing**

The medicine is issued without doctor's prescription.

### **Manufacturer**

Fairpharm Vertriebs GmbH, Am Krebsenbach 5-7, D-83670 Bad Heilbrunn, Germany