

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ESPUMISAN BABY

40 mg / ml oral drops, emulsion

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.*

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

#### 1. WHAT ESPUMISAN BABY IS AND WHAT IS IT USED FOR

ESPUMISAN BABY granules 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 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).
- As an anti-foaming agent after poisoning with detergents (Tensides).

#### 2. BEFORE YOU TAKE ESPUMISAN BABY

##### **Do not take ESPUMISAN BABY**

- If you are allergic (hypersensitive) to simethicone or any other ingredient of ESPUMISAN BABY (see section 6).

• Please keep in mind when administering Espumisan oral drops, emulsion to others that this may also apply to them.

### **Take special care with ESPUMISAN BABY**

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 BABY 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.

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.

### **Other warnings**

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.

ESPUMISAN BABY contains 34.6 mg of sodium in a dose of 20 ml. This should be taken into account in patients with restricted sodium intake.

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

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

| <b>Age group</b>         | <b>Dosage in drops (ml)</b>   | <b>Frequency</b>   |
|--------------------------|---|--------------------|
| Infants                  | 25 drops (equivalent to 1 ml) in every bottle before feeding, before or after every breastfeeding |                    |
| 1 to 6 years             | 25 drops (equivalent to 1 ml)   | 3 to 5 times a day |
| 6 to 14 years            | 25 – 50 drops (equivalent to 1-2 ml)  | 3 to 5 times a day |
| Over 14 years and adults | 50 drops (equivalent to 2 ml)   | 3 to 5 times a day |

It is also possible to take ESPUMISAN BABY oral drops, emulsion after operations.

ESPUMISAN BABY oral drops, emulsion is taken with or after meals, also before going to bed if necessary. Espumisan oral drops, emulsion should be taken for as long as the complaints persist. ESPUMISAN BABY 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".

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

- radiological and ultrasound examination:

|   |                                   |
|---|-----------------------------------|
| On the day before the examination       | On the morning of the examination |
| 3 times a day, 2 ml (that is, 50 drops) | 2 ml (that is, 50 drops)          |

- as a supplement to contrasting suspensions (which are used for diagnostic examinations of the stomach and intestine):

4-8 ml (100-200 drops) in 1 liter of contrast material in the double contrast method

- for the preparation for endoscopic examination of the upper part of the digestive system (esophagogastroduodenoscopy):

Before endoscopy, 4-8 ml (100-200 drops)

If necessary, a few ml of the emulsion can be induced through the tube of the endoscope to remove the interfering gas bubbles.

- As an anti-foaming agent after poisoning caused by detergents (surfactants)

Depending on the severity of poisoning:

| Age                                       | Dosage  |
|---|---|
| Children<br>Of the content of the bottle) | 2,5 - 10 ml (corresponding to 65 drops to 1/3             |
| Adults<br>the bottle)                     | 10 - 20 ml (corresponding to 1/3 to 2/3 of the content of |

Note: If you use ESPUMISAN BABY as a first-aid after swallowing detergent, immediately go to the doctor!

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

#### ***If you take more ESPUMISAN BABY than you should***

Taking too much ESPUMISAN BABY is unlikely to cause any ill effect. Even large quantities of ESPUMISAN BABY 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 BABY***

You can make up for the dose at any time.

#### ***If you stop taking ESPUMISAN BABY***

After you stop taking ESPUMISAN BABY, 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.

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

#### ***5. HOW TO STORE ESPUMISAN BABY***

Keep out of the reach and sight of children.

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

Espumisan 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 BABY contains**

The active ingredient is simethicone.  
25 drops (1 ml of oral emulsion) contain 40 mg of simethicone.

The other ingredients are: makrogolstearat; glycerol; carbomers; banana flavor; acesulfamkalij; Sorbitol, liquid, non-crystalline; sodium chloride; sodium citrate; sodium hydroxide; sorbic acid; Purified water.

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

Milky white emulsion of low viscosity.  
Espumisan Baby is available in a pack containing 30 ml of oral emulsion in a brown glass bottle with a dropper.

### **Regime of dispensing**

The medicine is issued without doctor's prescription.

### **Manufacturer**

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