

## Package leaflet: information for the user

### SPASMAG INJECTABLE, solution for injection (IV) in ampoule

Magnesium (sulphate) heptahydrate

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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.

Keep out of the reach of children

#### **In this leaflet:**

1. WHAT SPASMAG INJECTABLE, solution for injection (IV) in ampoule IS AND WHAT IT IS USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE YOU USE SPASMAG INJECTABLE solution for injection (IV) in ampoule?
3. HOW TO USE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?
6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### **1. WHAT SPASMAG INJECTABLE, solution for injection (IV) in ampoule IS AND WHAT IT IS USED FOR ?**

##### MAGNESIUM SALT SOLUTIONS

(B: Blood and Blood Forming Organs), ATC code: B05XA05

This medicine is indicated in the following situations:

- Curative treatment of torsades de pointes (*particular cardiac rhythm disorder*).
- Treatment of acute hypokalaemia (*abnormally low potassium level in the blood*) combined with hypomagnesaemia (*abnormally low magnesium level in the blood*).
- Intake of magnesium in the context of correction of fluid/electrolyte disorders.
- Intake of magnesium in the context of parenteral nutrition.
- Preventive and curative treatment of eclampsia (hypertension during child birth).

You must talk to a doctor if you do not feel better or if you feel worse.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?**

##### **Never use SPASMAG INJECTABLE, solution for injection (IV) in ampoule:**

- if you are allergic (hypersensitive) to the active substance
- If you have severe kidney failure.

*IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

##### **Be careful with SPASMAG INJECTABLE, solution for injection (IV) in ampoule:**

###### **Special warnings**

HYPERTONIC SOLUTION FOR SLOW INJECTION.

Comply with an infusion rate not exceeding 150 mg/minute of magnesium sulphate heptahydrate, i.e. 0.6 mmol/minute of elemental magnesium.

###### **Precautions for use**

- The first intravenous administrations are to be conducted in hospital.
- Monitor blood pressure during intravenous injection and continuous infusion.
- Monitor serum magnesium; discontinue treatment as of serum magnesium normalisation.
- Reduce the dosage for patients with kidney failure and intensify monitoring of renal function, blood pressure and serum magnesium (*magnesium concentration in the blood*).

*IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE*

### **Warnings and precautions**

Talk your doctor or pharmacist before using SPASMAG INJECTABLE, solution for injection (IV) in ampoule.

### **Other medicines and SPASMAG INJECTABLE, solution for injection (IV) in ampoule:**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy and Breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

In the absence of data, this product is only to be used during pregnancy and breast-feeding if necessary.

## **3. HOW TO USE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?**

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

### **Dosage**

STRICTLY COMPLY WITH MEDICAL ADVICE.

### **Method and route of administration**

- Either by **slow** direct intravenous injection with the patient supine and in medical care facilities;
- Or by intravenous infusion diluted in glucose or saline solution.

STRICTLY COMPLY WITH MEDICAL ADVICE

### **Frequency of administration**

STRICTLY COMPLY WITH MEDICAL ADVICE

### **Treatment duration**

STRICTLY COMPLY WITH MEDICAL PRESCRIPTION

### **If you use more SPASMAG INJECTABLE, solution for injection (IV) in ampoule than you should:**

The initial signs of overdose (hypermagnesaemia) consist in inhibition of the patellar reflexes, a feeling of heat, drowsiness, spoken language disorders, muscular paralysis with difficulty breathing and even respiratory and cardiac arrest.

In that context, the following treatment is to be instituted:

- Fluids, forced diuresis,
- IV injection of 1 g of calcium gluconate,
- Haemodialysis or peritoneal dialysis in the event of kidney failure.

Consult your doctor or pharmacist immediately.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- Pain at the injection site, vasodilatation with a feeling of heat,
- Potentially fatal hypermagnesaemia (*increase in the magnesium level in the blood*) in the event of severe kidney failure or excessively fast injection.

### **Reporting of side effects:**

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Web site: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?**

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 carton box after abbreviation used for expiry date. The expiry date refers to the last day of that month.

Shelf life after opening: the product should be used immediately.

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 does SPASMAG INJECTABLE, solution for injection (IV) in ampoule contain?**

The active substance is:

Magnesium sulphate heptahydrate ..... 1.20 g  
per 10 ml ampoule.

Osmolarity: 550 mOsm/l.

Mg<sup>++</sup>: 490 mmol/l i.e. 11800 mg/l,

4.9 mmol/ampoule i.e. 118 mg/ampoule.

The other ingredient is: water for injection

### **What is SPASMAG INJECTABLE, solution for injection (IV) in ampoule and contents of the outer pack?**

This medicine is a solution for injection. Box of 5 and 10 ampoules of 10 ml.

#### **Marketing Authorisation Holder:**

Laboratoires GRIMBERG SA – 44 Avenue Georges Pompidou – 92300 Levallois-Perret - France

#### **Manufacturer:**

Laboratoires GRIMBERG SA- ZA des Boutries - Rue Vermont - 78704 Conflans Sainte Honorine Cedex- France

This leaflet was last revised in August 2017.

Detailed information on this medicinal product is available on ANSM website (France)