

# PACKAGE LEAFLET

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

**Read all of this leaflet carefully before you start taking this medicine. It contains important information about your treatment.**

If you have any further questions, if you have any doubt, ask your doctor or pharmacist.

Keep this leaflet, you may need to read it again.

If you need further informations or advice, ask your pharmacist.

If your symptoms get worse or persist, consult a doctor.

If you notice any side effects not listed in this leaflet, or if any of the side effects gets serious, please tell your doctor or pharmacist.

### **In this leaflet:**

1. WHAT SPASMAG INJECTABLE, solution for injection (IV) in ampoule IS AND WHAT IT IS USED FOR ?
2. WHAT ARE THE INFORMATION TO BE AWARE OF BEFORE USING SPASMAG INJECTABLE solution for injection (IV) in ampoule?
3. HOW TO USE SPASMAG INJECTABLE, solution for injection (IV) in ampoule?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?
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### **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)

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).

### **2. WHAT ARE THE INFORMATION TO BE AWARE OF BEFORE USING SPASMAG INJECTABLE, solution for injection (IV) in ampoule?**

Never use SPASMAG INJECTABLE, solution for injection (IV) in ampoule in the following case:

- 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*

#### **Taking or using other medicines**

*IN ORDER TO AVOID POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, ALWAYS TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER ONGOING TREATMENT.*

### **Pregnancy - lactation**

In the absence of data, this product is only to be used during pregnancy or lactation if necessary.

IN GENERAL, DURING PREGNANCY OR LACTATION, ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE USING ANY MEDICINE.

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

#### **Dosage:**

STRICTLY COMPLY WITH MEDICAL ADVICE.

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

- Either by **slow** direct intravenous injection with the patient supine and conducted in a specialised setting.
- 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.

### **4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?**

Like all medicines, SPASMAG INJECTABLE, solution for injection (IV) in ampoule 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.

#### Statement of the side effects:

If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and health products (ANSM) and the Regional Centers of Pharmacovigilance. The web site: [www.ansm.sante.fr](http://www.ansm.sante.fr). By reporting the adverse events, you contribute to supply more information on the medicine safety.

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

Keep out of the reach and sight of children.

Do not use SPASMAG INJECTABLE, solution for injection (IV) in ampoule after the expiry date which is stated on the box.

After opening: the product should be used immediately.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

## 6. FURTHER 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 ingredients are:**

Water for injection.

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

Solution for injection. Box of 5 ampoules of 10 ml.

**Marketing Authorisation Holder and operating company:**

Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris - FRANCE

**Manufacturer:**

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

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