# SUMMARY OF PRODUCT CHARACTERISTICS

**NAME OF THE MEDICINAL PRODUCT**

**SPASMAG INJECTABLE, solution for injection (IV) in ampoule.**

**QUALITATIVE AND QUANTITATIVE COMPOSITION**
Magnesium sulphate heptahydrate ..... 1.20 g
per ampoule.

Osmolarity: 550 mOsm/l.
$Mg^{++}$: 490 mmol/l i.e. 11800 mg/l,
4.9 mmol/ampoule i.e. 118 mg/ampoule.

For a full list of excipients, see section “List of excipients”.

**PHARMACEUTICAL FORM:**
Solution for injection

**CLINICAL PARTICULARS**
**Therapeutic indications**
- Curative treatment of torsades de pointes.
- Treatment of acute hypokalaemia combined with hypomagnesaemia.
- Magnesium intake in the context of correction of fluid/electrolyte disorders.
- Magnesium intake in the context of parenteral nutrition.
- Preventive and curative treatment of eclampsia.

**Posology and method of administration**
**Posology**
*Curative treatment of torsades de pointes*
**Slow** direct intravenous injection of 2 g of magnesium sulphate heptahydrate (i.e. 8 mmol of elemental magnesium) in a few minutes at the discretion of the resuscitator, followed by intravenous infusion 3 to 20 mg/minute of magnesium sulphate heptahydrate (i.e. 0.012 to 0.08 mmol of elemental magnesium per minute).

*Preventive and curative treatment of eclampsia*
For the prevention of eclampsia or treatment of emergent eclampsia, administer an intravenous infusion of 4 g of magnesium sulphate heptahydrate (i.e. 16 mmol of elemental magnesium) over 30 minutes.
In the event of persistence of eclampsia, administer a further intravenous infusion of 4 g without exceeding a maximum total dose of 8 g of magnesium sulphate heptahydrate (i.e. 32 mmol of elemental magnesium) during the first hour of treatment.

Thereafter, administer by intravenous infusion 2 to 3 g of magnesium sulphate heptahydrate per hour (i.e. 8 to 12 mmol of elemental magnesium) over the 24 hours following the most recent episode.

*Treatment of acute hypokalaemia combined with hypomagnesaemia*
*Adult:*
Intravenous infusion of 6 to 8 g of magnesium sulphate heptahydrate (i.e. de 24 à 32 mmol of elemental magnesium) per 24 hours.
Potassium supplementation is to be administered from a container different from that used to administer magnesium. Treatment is to be discontinued as soon as serum magnesium has normalised.

*Child:*
The usual dosage of the intravenous infusion is 25 to 75 mg of magnesium sulphate heptahydrate per kg of body weight and per 24 hours (i.e. 0.1 to 0.3 mmol of elemental magnesium per kg of body weight and per 24 hours).

*Magnesium intake in the context of correction of fluid/electrolyte disorders and parenteral nutrition*
*Adult:*
Intravenous infusion of 1.5 to 2 g of magnesium sulphate heptahydrate (i.e. 6 to 8 mmol of elemental magnesium) per 24 hours.

*Child:*
The usual dosage of the intravenous infusion is 25 to 75 mg of magnesium sulphate heptahydrate per kg of body weight and per 24 hours (i.e. 0.1 to 0.3 mmol of elemental magnesium per kg of body weight and per 24 hours).

**Summary of dosages in different indications**

<table>
<tr><th colspan="2">INDICATION</th><th>ROUTE</th><th>FLOW RATE<br>magnésium sulphate heptahydrate in mg/min<br>(elemental magnésium in mmol)/min</th></tr>
<tr><td rowspan="2">Curative treatment of torsades de pointes</td><td>From the outset</td><td>Slow direct IV injection</td><td>2 g (8 mmol) in a few minutes at the discretion of the resuscitator</td></tr>
<tr><td>Then</td><td>IV infusion</td><td>3 to 20 mg (0,012 à 0,08 mmol)/min</td></tr>
<tr><td rowspan="3">Preventive and curative treatment of eclampsia</td><td>For the prevention of eclampsia or treatment of emergent eclampsia</td><td rowspan="3">IV infusion</td><td>4 g (16 mmol) in 30 min<br><br>i.e. 133 mg (0,53 mmol)/min</td></tr>
<tr><td>If persistence of eclampsia</td><td>4 g (16 mmol) without exceeding a maximum total dose of 8 g (32 mmol) during the first hour of treatment<br><br>i.e. 66 to 133 mg (0,26 to 0,53 mmol)/min (first hour)</td></tr>
<tr><td>Thereafter</td><td>2 to 3 g (8 to 12 mmol)/h over the 24 hours following the most recent episode<br><br>i.e. 33 to 50 mg (0,13 to 0,2 mmol)/min (24 h)</td></tr>
<tr><td colspan="2" rowspan="2">Treatment of acute hypokalaemia combined with hypomagnesaemia</td><td rowspan="2">IV infusion</td><td><u>Adult</u> : 6 to 8 g (24 to 32 mmol)/24 h<br><br>i.e. 4 to 5 mg (0,016 to 0,022 mmol)/min (24h)</td></tr>
<tr><td><u>Child</u> : 25 to 75 mg/Kg/24h<br><br>(0,1 to 0,3 mmol/Kg/24h)</td></tr>
<tr><td colspan="2" rowspan="2">Magnesium intake in the context of correction of fluid/electrolyte disorders and parenteral nutrition</td><td rowspan="2">IV infusion</td><td><u>Adult</u> : 1,5 to 2 g (6 to 8 mmol)/24 h<br><br>i.e. 1 to 1,4 mg (0,004 to 0,005 mmol)/min (24h)</td></tr>
<tr><td><u>Child</u> : 25 to 75 mg/Kg/24h<br><br>(0,1 to 0,3 mmol/Kg/24h)</td></tr>
</table>

<u>As a general rule for IV infusion in adult:</u>

In order to prevent potentially fatal hypermagnesaemia, flow rate of the intravenous infusion is not to exceed 150 mg/minute of magnesium sulphate heptahydrate (i.e. 0.6 mmol of elemental magnesium par minute).

**Method of administration**
The solution of magnesium sulphate heptahydrate is to be administered:

- Either by **slow** direct intravenous injection with the patient supine and conducted in a specialised setting (intensive care unit, cardiological ICU).This method of administration is restricted to the treatment of torsades de pointes.
- Or by intravenous infusion diluted in glucose or saline solution.

**Contraindications**
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
Severe kidney failure (creatinine clearance less than 30 mL/min/1.73 $m^2$).

**Special warnings and precautions for use**
HYPERTONIC SOLUTION FOR SLOW INJECTION.

- The first intravenous administrations are to be conducted in hospital.
- Comply with an infusion rate not exceeding 150 mg/minute of magnesium sulphate heptahydrate, i.e. 0.6 mmol/minute of elemental magnesium.
- 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.

**Interactions with other medicinal products and other forms of interaction**
The data available to date do not suggest the existence of clinically significant interactions

**Fertility, pregnancy and lactation**
***Pregnancy***
In clinical practice, no malformation-inducing or foetotoxic effect has been observed to date.
However, the follow up of pregnancies exposed to magnesium salts administered by the IV route is not sufficient to rule out all risk.
In consequence, use of the product during pregnancy is only to be envisaged if necessary.
***Lactation***
In the absence of data on potential magnesium excretion in breast milk, it is preferable not to breast feed during treatment.

**Effects on ability to drive and use machines**
No study of the effects on the capacity to drive vehicles and to use machines was carried out. However, no effect on this matter is expected.

**Undesirable effects**
- Pain at the injection site, vasodilatation with a feeling of heat.
- Potentially fatal hypermagnesaemia in the event of severe kidney failure or excessively fast injection.

Reporting of suspected undesirable effects
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: Agence nationale de sécurité du medicament et des produits de santé (ANSM) and network of the Regional Centres of Pharmacovigilance – Website: www.signalement-sante.gouv.fr

**Overdose**
The initial signs of 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.

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

## PHARMACOLOGICAL PROPERTIES

**Pharmacodynamic properties**
Pharmacotherapeutic group: MAGNESIUM SALT SOLUTIONS.
ATC code: B05XA05
(B: Blood and Blood Forming Organs).

***At physiological level***
Magnesium is a mainly intracellular cation. Magnesium decreases neuronal excitability and neuromuscular transmission.
Magnesium is involved in numerous enzymatic reactions.
Magnesium is a constitutional element: 50% of the magnesium in the body is found in the bone.

***At clinical level***, serum magnesium:
- between 12 and 17 mg/l (1 to 1.4 mEq/l or 0.5 to 0.7 mmol/l) indicates moderate magnesium deficiency;
- less than 12 mg/l (1 mEq/l or 0.5 mmol/l) indicates severe magnesium deficiency.

Magnesium deficiency may be:
- either primary due to a congenital abnormality of metabolism (chronic congenital hypomagnesaemia),
- or secondary due to:
  - insufficient intake (severe denutrition, alcoholism, exclusive parenteral nutrition),
  - digestive malabsorption (chronic diarrhoea, digestive fistula, hypoparathyroidism),
  - excessive renal losses (tubule disease, marked polyuria, abuse of diuretics, chronic pyelonephritis, primary hyperaldosteronism, cisplatin treatment).

Non-specific clinical manifestations may occur in the context of magnesium deficiency: tremor, muscle weakness, tetany, ataxia, hyperreflexia, psychological disorders (irritability, nervousness, insomnia, etc.), cardiac rhythm disorders (extra-systoles, tachycardia), and gastrointestinal disorders (diarrhoea, etc.).

**Pharmacokinetic properties:**
Excretion is primarily urinary.

**Preclinical safety data:**
No information is available.

## PHARMACEUTICAL PARTICULARS

**List of excipients:**
Water for injection

**Incompatibilities:**
In the absence of compatibility study, this medicine must not be mixed with other medicines, the ones indicated in the section “Posology and method of administration”.

**Shelf life:**
5 years.
After opening: the product should be used immediately

**Special precautions for storage:**
No special precautions for storage are required.

**Nature and contents of external container:**
10-ml ampoule (glass). Box of 5 and 10 ampoules

**Method of use, instructions for handling:**
Any unused product or waste material should be disposed of in accordance with current regulations.

**MARKETING AUTHORISATION HOLDER**
Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

**8 MARKETING AUTHORISATION NUMBERS**

- 34009 328 761 1 2: 10-ml glass ampoules. Box of 5
- 34009 300 830 6 2:10-ml glass ampoules. Box of 10

**9. DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION**
21 October 1982/21 October 2012

**10. DATE OF REVISION OF THE TEXT**
10 August 2017

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**PRESCRIBING AND DISPENSING CONDITIONS**

Medicinal product is not subject to medical prescription