SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SPASMAG, oral solution in an ampoule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ampoule:

Active substances:
Magnesium sulphate heptahydrate ..... 1.200 g
quantity equivalent to elemental magnesium ..... 0.118 g
Saccharomyces cerevisiae yeast..... 0.100 g
Per 5 ml ampoule

Excipients:
Anhydrous citric acid, Sodium cyclamate, Saccharin sodium, Orange flavour*, Purified water.

* Composition of the orange flavour: essential oil of sweet orange peel, alcohol.

3. PHARMACEUTICAL FORM:

Oral solution in an ampoule.

4. CLINICAL DATA

4.1. Therapeutic indications: Proven, isolated or combined magnesium deficiency.

4.2. Posology and method of administration

Posology
Oral route.
In adults: 3 ampoules daily.
In children: 9.6 to 28.8 mg/kg/d, i.e. 1 to 3 ampoules daily.
The ampoules are to be shaken and their contents diluted in a little water, preferably to be taken as several intakes before or during a meal.
The usual treatment duration is 1 month.

4.3. Contra-indications

This medicinal product is contra-indicated in the event of:
• hypersensitivity to one of the ingredients
• severe kidney failure (creatinine clearance less than 30 ml/min/1.73 m^2).

4.4. Special warnings and precautions for use

Special warnings
In the event of severe deficiency, treatment is to be initiated by the intravenous route. The same applies in the event of malabsorption.
In the event of combined calcium deficiency, in most cases it is recommended to conduct magnesium supplementation first followed by calcium supplementation.

4.5. Interactions with other medicinal products and other forms of interaction: Not applicable.

4.6. Pregnancy and lactation

Pregnancy

There are no reliable animal teratogenicity data.
In clinical practice, analysis of a high number of exposed pregnancies did not evidence any particular malformation-inducing or foetotoxic effect of magnesium. However, only epidemiological studies would enable verification of the absence of risk.
Given the clinical experience, use of the medicinal product may be envisaged at any term during pregnancy.
Lactation: Due to magnesium excretion in breast milk, use of magnesium is to be avoided during lactation.

4.7. Effects on the ability to drive and use machines: Not applicable.

4.8. Adverse effects

• Diarrhoea,
• Abdominal pain.

Reporting of suspected adverse reactions

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 Agence nationale de sécurité du medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.ansm.sante.fr

4.9. Overdose: In the event of massive intake, risk of an anuric syndrome.
Treatment: fluids, forced diuresis. In the event of kidney failure, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class:

MINERAL SUPPLEMENT– ATC code: A 12
(A: gastrointestinal system and metabolism)

At physiological level:

Magnesium is a mainly intracellular cation. Magnesium decreases neuronal excitability and neuromuscular transmission and is involved in numerous enzymatic reactions.
A constitutional element, half 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:

• primary due to a congenital abnormality of metabolism (chronic congenital hypomagnesaemia),
• 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).

5.2. Pharmacokinetic properties
The digestive absorption of magnesium salts is, in part, a passive mechanism in which the solubility of the salt is decisive. Digestive absorption of magnesium salts does not exceed 50%.
Excretion of magnesium is primarily urinary.

5.3. Preclinical safety data: Not applicable.

6. PHARMACEUTICAL DATA

6.1. Incompatibilities: Not applicable.

6.2. Shelf life: 3 years.

6.3. Special precautions for storage: Not applicable.

6.4. Nature and contents of container: 5-ml ampoule (brown glass); box of 24 or 30.

6.5. Method of use, instructions for handling: Not applicable.

7. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

3400932857760 or 328 577-6: 5-ml ampoule (brown glass); box of 24 - Not marketed
3400932926350 or 329 263-5: 5-ml ampoule (brown glass); box of 30.- Marketed

8. PRESCRIBING AND DISPENSING CONDITIONS: Medicinal product not subject to medical prescription

9. MARKETING AUTHORISATION HOLDER
Laboratoires GRIMBERG - 19, rue Poliveau - 75005 PARIS – France

10. DATE OF APPROVAL / REVISION: 5th October 2006.