SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

SPASMAG, oral solution in ampoule

QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient with known effect: ethanol
For the full list of excipients, see the section “List of excipients”.

PHARMACEUTICAL FORM

Oral solution in ampoule.

CLINICAL PARTICULARS

Therapeutic indications

Proven, isolated or combined magnesium deficiency.

Posology and method of administration

Oral route

Posology

Pediatric population:
9.6 to 28.8 mg/kg/d, i.e. 1 to 3 ampoules daily.
Adults:
3 ampoules daily.

Method of administration
The ampoules are to be shaken and their contents diluted in a little bit of water, preferably to be taken in several intakes before or during a meal.

Treatment duration
The usual treatment duration is 1 month.

Contra-indications

Hypersensitivity to the active substances or to one of the excipients listed in the section “List of excipients”.
Severe kidney failure (creatinine clearance less than 30 ml/min/1.73 m^2).

Special warnings and precautions for use

In case of severe deficiency, treatment is to be initiated by intravenous route. The same applies in case of malabsorption.
In case of combined calcium deficiency, in most cases it is recommended to conduct magnesium supplementation first before calcium therapy.
This medicine contains 304 mg of alcohol (ethanol) in each ampoule. The amount in volume of this medicine is equivalent to less than 8 ml beer or 3 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium free'.

Fertility, 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.

Breast-feeding
Due to magnesium excretion in breast milk, use of magnesium is to be avoided during lactation.

Undesirable effects
• Diarrhoea,
• Abdominal pain

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
In case of massive intake, risk of an anuric syndrome

Treatment**:** fluids, forced diuresis. In case of kidney failure, haemodialysis or peritoneal dialysis is necessary.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class*:* MINERAL SUPPLEMENT– ATC code: A12CC02

Mechanism of action

At physiological level:

Magnesium is a mainly intracellular cation. Magnesium decreases neuronal excitability and neuromuscular transmission and is involved in numerous enzymatic reactions.
As constitutional element, half of the total body magnesium is found in bone.

At clinical level, serum magnesemia:

• included between 12 and 17 mg/l (1 to 1.4 mEq/l or 0.5 to 0.7 mmol/l) indicates moderate magnesium deficiency;
• below 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).

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 mainly urinary.

PHARMACEUTICAL PARTICULARS

List of excipients
Anhydrous citric acid, Sodium cyclamate, Saccharin sodium, Orange flavour*, Purified water.

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

Shelf life:
3 years.

Special precautions for storage
This medicine does not require any special conditions of storage.

Nature and contents of external container
5-ml ampoule (brown glass) with two self-breaking points; box of 30 ampoules.

Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

MARKETING AUTHORISATION NUMBERS
3400932926350: 5-ml ampoule (brown glass); box of 30

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION
21 September 1976/21 September 2011

DATE OF REVISION OF THE TEXT
18 November 2020

PRESCRIBING AND DISPENSING CONDITIONS
Medicinal product is not subject to medical prescription