SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

SPASMAG, capsule

QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium sulphate trihydrate ..... 423.5 mg
quantity equivalent to elemental magnesium ..... 59.0 mg
Saccharomyces cerevisiae yeast ..... 50.0 mg
Per one capsule

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

PHARMACEUTICAL FORM

Capsule.

CLINICAL PARTICULARS

Therapeutic indications

This medicine contains some magnesium and some typical yeast Saccharomyces cerevisiae.

The combination of a number of the following symptoms may suggest of magnesium deficiency:
- Nervousness, irritability, mild anxiety, transient tiredness, minor sleep disorders
- Signs of anxiety such as digestive cramps or palpitations (healthy heart)
- Muscle cramps, tingling

Magnesium supplementation may improve these symptoms.
In case of absence of improvement of these symptoms after one month, the treatment will be reassessed.

Posology and method of administration

Posology
Oral route

For adults and children of over 12 years old.

Children from 12 years old:
2 to 6 capsules daily

Adults:
6 capsules daily

The capsules are to be swallowed with a little bit of water, preferably in several intakes before or during a meal.
If a patient wishes, the capsule may be opened and its contents mixed with a liquid.
The usual treatment duration is 1 month.

Contra-indications

• Hypersensitivity to the active substances or to any of the excipients listed in section “List of excipients”
• severe kidney failure (creatinine clearance less than 30 mL/min/1.73 m²),
• children of less than 12 years old
• in case of phenylketonuria due to the presence of aspartame.

Special warnings and precautions for use

This medicine is for an adult and a child of over 12 years old.
In case of absence of improvement of these symptoms after one month, the treatment will be reassessed.

Interactions with other medicinal products and other forms of interactions
The data available presently do not show any interactions clinically meaningful.

Fertility, pregnancy and breast-feeding
Pregnancy
There are no reliable teratogenicity data in animal.

In clinical practice, the analysis of high number of exposed pregnancies did not show 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 breast-feeding.

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 a massive intake, there is a risk of an anuric syndrome.

Treatment
Rehydration, forced diuresis. In case of kidney failure, a haemodialysis or a peritoneal dialysis is necessary.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
MINERAL SUPPLEMENT –ATC code: A12CC02
(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.
As a constitutional element, half of the total body magnesium is found in bone.

At clinical level, serum magnesemia:

• 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),
    - intestinal malabsorption (chronic diarrhoea, gastrointestinal tract fistula, hypoparathyroidism),
    - excessive renal losses (tubule disease, marked polyuria, abuse of diuretics, chronic pyelonephritis, primary hyperaldosteronism, cisplatin treatment).

Pharmacokinetic properties

The intestinal absorption of magnesium salts is, in part, a passive mechanism in which the solubility of the salt is decisive. Intestinal absorption of magnesium salts does not exceed 50%.
Excretion is mainly urinary.

Preclinical safety data

No information is available.

PHARMACEUTICAL PARTICULARS

List of excipients

Magnesium stearate, Aspartame (E951), Orange flavour*

Composition of the capsule shell: gelatin, titanium dioxide (E171), indigotin (E132).
* Composition of the orange flavour: maltodextrin, soy proteins, acacia, concentrated orange juice, essential oil of orange, essential oil of lemon, citral, acetaldehyde, linalol, ethyl butyrate, alpha-terpineol, octanal, ethyl acetate, geranyl acetate.

Shelf life

3 years.

Special precautions for storage

No special precautions for storage.

Nature and contents of external container

60 capsules in blisters (PVC/PE/PVDC/Aluminium)

Special precautions for disposal and other handling

Any unused 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 NUMBER(S)

34009 323 690 9 6: 60 capsules in blisters (PVC/PE/PVDC/Aluminium).

DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

6 May 1980 /06 May 2010

DATE OF REVISION OF THE TEXT:

10 August 2017

PRESCRIBING AND DISPENSING CONDITIONS

This medicinal product is not subject to medical prescription.