SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SPASMAG, capsule

2. 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 capsule

For the full list of excipients: see the section 6.1

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL PARTICULARS

4.1 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 within one month, the treatment will be re assessed.

4.2 Posology and method of administration

Oral route.

For adults and children aged 12 years old and older.

Children from 12 years old on: 2 to 6 capsules daily
Adults: 6 capsules daily.

The capsules are to be swallowed with a little water, preferably as several intakes before or during a meal.
A capsule may be opened and its contents mixed with a liquid.

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 m²),
• children aged less than 12 years old
• in the event of phenylketonuria due to the presence of aspartame.

4.4 Special warnings and precautions for use

Special warnings

This medicine is for an adult and a child aged 12 years old and older.

In case of absence of improvement of these symptoms within one month, the treatment will be re assessed.

4.5 Interactions with other medicinal products and other forms of interaction

The data available presently do not show any interactions clinically meaningful.

4.6 Pregnancy and lactation

Pregnancy

There are no reliable animal teratogenicity data.

In clinical practice, analysis of 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 Undesirable 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 case of a massive intake, there is a risk of an anuric syndrome.

Treatment: fluids, forced diuresis. In case 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),
  • intestinal malabsorption (chronic diarrhoea, gastrointestinal tract fistula, hypoparathyroidism),
  • excessive renal losses (tubule disease, marked polyuria, abuse of diuretics, chronic pyelonephritis, primary hyperaldosteronism, cisplatin treatment).

5.2 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 primarily urinary.

5.3 Preclinical safety data

Unspecified.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, Aspartame, 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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

60 capsules in heat-formed blister packs (PVC/PE/PVDC/Aluminium)

6.6 Method of use, instructions for handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG
19, rue Poliveau

75005 PARIS
France

8. ADMINISTRATIVE IDENTIFICATION NUMBERS

323 690-9 or 34009 323 690 9 6: 60 capsules in blister strips (PVC/PE/PVDC/Aluminium).

9. DATE OF MA APPROVAL

06 May 1980

10. UPDATE OF THE TEXT

25 October 2013

PRESCRIBING AND DISPENSING CONDITIONS

This medicinal product is not subject to medical prescription.