

Package leaflet: information for the user

SPASMAG, hard capsule Magnesium, *Saccharomyces cerevisiae* yeast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to your doctor if you do not feel better or if you feel worse

What is in this leaflet

1. WHAT SPASMAG, hard capsule IS AND WHAT IT IS USED FOR
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1. WHAT SPASMAG, hard capsule IS AND WHEN IT IS USED FOR

Pharmacotherapeutic group: MINERAL SUPPLEMENT– ATC code: A12CC02

This medicine is indicated in adults and children from 12 years old

This medicine contains magnesium and *Saccharomyces cerevisiae* yeast.

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.

You should speak to your doctor if you do not feel any improvement or if you feel worse after 1 month of treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPASMAG, hard capsule

Do not take SPASMAG, hard capsule

- If you are allergic hypersensitive to the active substances or any of the other ingredients of this medicine listed in section 6
- In case of severe kidney failure (defective function of the kidneys).
- In children less than 12 years old,
- In case of phenylketonuria (hereditary disease detected at birth) due to the presence of aspartame.
- In case of allergy to soy or to peanuts

Warnings and precautions

Talk to your doctor or pharmacist before taking SPASMAG, hard capsule.

Other medicines and SPASMAG, hard capsule

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

This medicine will be used during pregnancy with medical advice only.

If you discover that you are pregnant during treatment, consult your doctor since only he/she can decide whether you should pursue treatment.

Breast-feeding:

Use of this medicine during breast-feeding is to be avoided.

Ask your doctor or pharmacist for advice before taking any medicine.

SPASMAG, capsule contains: aspartam and soy proteins.

This medicine contains 8 mg of aspartam per capsule.

Aspartam is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

If you are allergic to peanut or soy, do not use this medicinal product.

3. HOW TO TAKE SPASMAG, hard capsule

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- Children from 12 to 15 years old: 2 to 6 capsules daily.
- Adults: 6 capsules daily

Method of administration

Oral route.

Swallow the capsules with a little water. If necessary, the capsules can be opened and their contents mixed with a liquid.

Administration frequency

The daily dose is to be taken as several intakes before or during a meal.

Treatment duration

The usual treatment duration is 1 month.

In case of absence of improvement of the symptoms within one month, there is no use of continuing treatment. Consult your doctor.

Use in children and adolescents

For adults and children aged from 12 years old

If you use more SPASMAG, hard capsule than you should:

Consult your doctor or pharmacist immediately

If you forget to take SPASMAG, hard capsule:

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- diarrhoea,
- abdominal pain

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system: . By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SPASMAG, hard capsule

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton box after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SPASMAG, hard capsule contains

- The active substances are:
Magnesium sulphate trihydrate 423.5 mg
quantity equivalent to elemental magnesium 59.0 mg
Saccharomyces cerevisiae yeast 50.0 mg
Per a hard capsule

- The other ingredients are:
Magnesium stearate, Aspartam, 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 orange oil, essential lemon oil, citral, acetaldehyde, linalol, ethyl butyrate, alpha-terpineol, octanal, ethyl acetate, geranyl acetate.

What SPASMAG, hard capsule looks like and contents of the pack?

This medicine is a capsule. Box of 60 capsules.

Marketing Authorisation Holder :

Laboratoires GRIMBERG SA – 44, Avenue Georges Pompidou, 92300 Levallois-Perret – FRANCE

Manufacturer:

Laboratoires GRIMBERG SA - ZA des Boutries - Rue Vermont - 78704 Conflans Sainte Honorine Cedex-FRANCE

This leaflet was last approved in November 2020