

PACKAGE LEAFLET

SPASMAG, capsule

Read all of this leaflet carefully before you start using this medicine. It contains important information for your treatment

This medicine is a specialty of self-medication which can be used without consultation nor prescription of a physician

If you have any further questions, if you have any doubt, ask your doctor or pharmacist

- . Keep this leaflet, you may need to read it again.
- . If you need further information and advices, please ask your pharmacist.
- . If symptoms worsen or persist after 1 month of treatment, consult your doctor.
- . If you notice any side effects not listed in this leaflet or if any of the side effects gets serious, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT SPASMAG, capsule IS AND WHAT IT IS USED FOR ?
2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING SPASMAG, capsule?
3. HOW TO USE SPASMAG, capsule?
4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?
5. HOW TO STORE SPASMAG, capsule?
6. FURTHER INFORMATION

1. WHAT SPASMAG IS AND WHEN IT IS USED FOR ?

MINERAL SUPPLEMENT (A: gastrointestinal system and metabolism)

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

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, ask your doctor or pharmacist for advice.

2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING SPASMAG ?

SPASMAG must not be used:

- If you are allergic (hypersensitive) to the active substances or one of the ingredients contained in SPASMAG
- In the event of severe kidney failure (defective function of the kidneys).
- In children aged less than 12 years,
- In the event of phenylketonuria (hereditary disease screened for at birth) due to the presence of aspartame.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy

This medicine is only to be used during pregnancy if your doctor advises you to do so. If you discover that you are pregnant during treatment, consult your doctor since only he/she can decide whether you should pursue treatment.

Lactation

Use of this medicine during lactation is to be avoided.

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

Excipients with a known effect

Aspartame

3. HOW TO USE SPASMAG ?

Posology

For adults and children aged from 12 years.

Adults:

6 capsules daily

Children aged from 12 to 15 years:

2 to 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.

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, it is of no value pursuing treatment. Consult your doctor.

IF IN DOUBT, CONSULT YOUR DOCTOR OR PHARMACIST.

If you use more SPASMAG, than you should:

Immediately consult your doctor or pharmacist.

If you forget to take SPASMAG:

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS ?

Like all medicines, SPASMAG, capsule can cause side effects, although not everybody gets them:

- diarrhoea,
- abdominal pain

Statement of the side effects:

If you feel any adverse effect, tell it to your doctor or your pharmacist. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and

health products (Ansm) and the Regional Centers of Pharmacovigilance. The web site: www.ansm.sante.fr. By reporting the adverse events, you contribute to supply more information on the medicine safety.

5. HOW TO STORE SPASMAG ?

Keep out of the reach and sight of children.

Do not use SPASMAG, capsule, after the expiry date which is stated on the box.

No special storage conditions.

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What does SPASMAG, contain ?

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 capsule

The other ingredients are:

Magnesium stearate, aspartame, orange flavour

Composition of the capsule shell: gelatin, titanium dioxide (E171), indigotin (E132).

What is SPASMAG and contents of the outer pack ?

This medicine contains 60 capsules.

Holder and operating company:

Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris - FRANCE

Manufacturer:

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

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