

PACKAGE LEAFLET

SPASMAG, oral solution.

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

- This medicine is available without a doctor's consultation or prescription.
- The persistence of the symptoms, their exacerbation or the emergence of new disorders requires a medical opinion.
- Keep this leaflet, you may need to read it again.

If you need further information or advice, ask your pharmacist or doctor.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 5-ml ampoule:

Active substances:

Magnesium sulphate heptahydrate.....1.200 g

quantity equivalent to elemental magnesium.....0.118 g

Saccharomyces cerevisiae yeast0.100 g

Excipients: Anhydrous citric acid, sodium cyclamate, saccharin sodium, orange flavour *, purified water.

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

PHARMACEUTICAL FORM: Oral solution in an ampoule.

PHARMACOTHERAPEUTIC CLASS: MINERAL SUPPLEMENT (A: gastrointestinal system and metabolism)

NAME AND ADDRESS OF THE OPERATOR: Laboratoires GRIMBERG - 19, rue Poliveau - 75005 PARIS –France

NAME AND ADDRESS OF THE MANUFACTURER: Laboratoires GRIMBERG – Z.A. des Boutries, 5 rue Vermont 78700 Conflans Sainte Honorine –France

WHEN IS THIS MEDICINE USED ?

(THERAPEUTIC INDICATIONS)

This medicine is indicated for magnesium deficiency confirmed by your doctor.

BEWARE!

WHEN IS THIS MEDICINE NOT USED ?

(CONTRA-INDICATIONS)

This medicine **MUST NOT BE USED:**

- If you are allergic (hypersensitive) to the active substances or one of the ingredients contained in SPASMAG, oral solution in an ampoule,
- In the event of severe kidney failure (defective function of the kidneys).

IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNINGS

- In the event of severe deficiency, treatment is to be initiated by the intravenous route. The same applies in the event of malabsorption.
- In the event of combined calcium deficiency, in most cases it is recommended to conduct magnesium supplementation first.

PRECAUTIONS FOR USE

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

If you are taking or have recently taken another medicine, including a medicine obtained without a prescription, tell your doctor or pharmacist.

IN ORDER TO AVOID POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, ALWAYS TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER ONGOING TREATMENT.

PREGNANCY - LACTATION

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.

IN GENERAL, DURING PREGNANCY OR LACTATION, ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE USING ANY MEDICINE.

HOW TO USE THIS MEDICINE ?

DOSAGE

The usual dosage is:

- **adults**: 3 ampoules daily.
- **children**: 1 to 3 ampoules daily.

METHOD AND ROUTE OF ADMINISTRATION: Oral route. The ampoules are to be shaken and their content diluted in a little water.

FREQUENCY AND TIME AT WHICH THE MEDICINE IS TO BE ADMINISTERED:

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

TREATMENT DURATION:

The usual treatment duration is 1 month.

If the symptoms are not alleviated after 1 month of treatment, it is of no value pursuing treatment. Consult your doctor.

IF IN DOUBT, CONSULT YOUR DOCTOR OR PHARMACIST.

WHAT TO DO IF YOU HAVE TAKEN AN OVERDOSE: Immediately consult your doctor or pharmacist

WHAT TO DO IF ONE OR SEVERAL DOSES HAVE BEEN OMITTED: Do not take a double dose to make up for the dose you forgot

UNPLEASANT SIDE EFFECTS

LIKE ANY ACTIVE PRODUCT, THIS MEDICINE MAY INDUCE MORE OR LESS UNPLESANT EFFECTS IN CERTAIN PEOPLE:

- diarrhoea,
- abdominal pain.

Statement of the side effects:

If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. 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.

STORAGE

DO NOT USE AFTER THE EXPIRY DATE WHICH IS STATED ON THE OUTER PACKAGING

DATE OF LEAFLET REVISION: 5th October 2006