

Package leaflet: information for the user

SPASMAG, oral solution in ampoule

Magnesium sulphate, 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 a doctor if you do not feel better or if you feel worse.

Keep out of the reach of children

What does this leaflet contain?:

1. WHAT SPASMAG, oral solution in ampoule IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPASMAG, oral solution in ampoule
3. HOW TO TAKE SPASMAG, oral solution in ampoule
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE SPASMAG, oral solution in ampoule
6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT SPASMAG, oral solution in ampoule IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: MINERAL SUPPLEMENT (A: digestive system and metabolism)
ATC code: A12CC02

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

You must talk to your doctor if you do not feel better or if you feel worse.

2. .WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPASMAG, oral solution in ampoule

Do not use SPASMAG, oral solution in ampoule:

- if you are allergic (hypersensitive) to the actives 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).

Warnings and precautions

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

Talk to your doctor or pharmacist before taking SPASMAG, oral solution in ampoule.

Other medicines and SPASMAG, oral solution in ampoule:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and Breast-feeding

Pregnancy:

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.

Breast-feeding:

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

3. HOW TO TAKE SPASMAG, oral solution in ampoule?

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

Posology

Use in adults:

The recommended dose is 3 ampoules daily

Use in children and adolescents

The recommended dose is 1 to 3 ampoules daily

Method and route of administration

Oral route. The ampoules are to be shaken and their contents 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.

In the absence of symptom improvement after one month of treatment, there is no need to continue treatment. Consult your doctor.

IF IN DOUBT, CONSULT YOUR DOCTOR OR PHARMACIST.

If you take more SPASMAG, oral solution in ampoule than you should:

Consult your doctor or pharmacist immediately.

If you forget to take SPASMAG, oral solution in ampoule

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 the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Website: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SPASMAG, oral solution in ampoule

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

Do not use this medicine after the expiry date which is stated on the cardboard 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 does SPASMAG, oral solution in ampoule contain

- The active substances are:
Magnesium sulphate heptahydrate 1,200 g
quantity equivalent to elemental magnesium 0,118 g

Saccharomyces cerevisiae yeast 0,100 g

- The other ingredients are: citric acid anhydrous, sodium cyclamate, sodium saccharin, orange flavour*, purified water

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

What SPASMAG, oral solution in ampoule looks like and contents of the pack?

Oral solution in ampoule

5 ml in ampoule (brown glass): box of 30

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 revised in August 2017.

Detailed information on this medicine is available on ANSM website (France)