

PACKAGE LEAFLET: Information for the patient

SULFAT MAGNEZI

Solution for injection – 2500 mg / 10 ml (25%)

(Magnesium sulphate)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. What Sulfat magnezi is and what it is used for
2. What you need to know before you take Sulfat magnezi
3. How to take Sulfat magnezi
4. Possible side effects
5. How to store Sulfat magnezi
6. Other information

1. WHAT SULFAT MAGNEZI IS AND WHAT IT IS USED FOR

Magnesium prevents or controls convulsions by blocking neuromuscular impulse transmission by decreasing the amount of acetylcholine released by the motor nerve impulse. Magnesium has a depressing effect on the central nervous system. Normal magnesium plasma levels are 1.5 – 3 mEq/l. 1 g magnesium sulphate contains 8.12 mEq magnesium.

Sulfat magnezi 2500 mg / 10 ml solution for injection is indicated in:

- prevention and control of convulsions in pre-eclampsia or severe eclampsia without causing harmful depression of central nervous system of the mother or baby and of convulsions associated with hypomagnesaemia;
- control of hypertension, encephalopathy and convulsions in children with acute nephritis;
- inhibition of preterm labour;
- treatment of life-threatening ventricular arrhythmias;

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SULFAT MAGNEZI

Do not take Sulfat magnezi:

- if you are allergic to magnesium sulphate;
- if you are pregnant, during the 2 hours preceding delivery;
- if you suffer from heart diseases.

Take special care with Sulfat magnezi

Talk to your doctor or pharmacist before taking Sulfat magnezi if you have renal insufficiency because it may lead to magnesium intoxication.

Sulfat magnezi solution for injection should be administered with special care in patients with severe muscle disease (myasthenia gravis).

Magnesium sulphate solution for injection is injected IV in eclampsia, only for immediate control of life-threatening convulsions.

Intramuscular injection is painful.

The patient should be monitored for clinical signs of magnesium overdose (See Side effects).

There is evidence that continuous administration of magnesium sulphate injection beyond 5 – 7 days in pregnancy for the treatment of pre – term labour can cause low calcium level and bone changes in the baby.

Other medicines and Sulfat magnezi

Use of other medicines with Sulfat magnezi can influence its effect or the other medicine's effect.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines without prescription. Inform your doctor that you are taking Sulfat magnezi if any other medicine is prescribed to you during treatment.

It is **particularly important** that you inform your doctor that you are taking the following medicines:

- neuromuscular blockers;
- nifedipine; profound hypotension has been reported with concomitant use of parenteral magnesium and nifedipine in pre-eclampsia;
- CNS depressant drugs;
- drugs to treat heart problems (cardiac glycosides), which may cause severe rhythm disorders;
- some drugs that are used to treat infections (aminoglycoside antibiotics).

Taking Sulfat magnezi with food and drinks

No available data.

Pregnancy

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

Magnesium sulphate should not be used in pregnancy during the 2 hours preceding delivery.

There is evidence that continuous administration of magnesium sulphate injection beyond 5 – 7 days in pregnancy for the treatment of pre-term labour can cause low calcium level and bone changes in the baby.

Breastfeeding

Safety during breastfeeding has not been established. Therefore, it is not advisable to administer magnesium sulphate during breast-feeding unless considered essential.

Driving and using machines

This medicine does not affect the ability to drive or use machinery.

3. HOW TO TAKE SULFAT MAGNEZI

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that the effect of Sulfat magnezi is too strong or too weak, talk to your doctor or pharmacist.

When administered intravenously, the solution should be diluted.

Intramuscular injection: 8 to 10 ml of the 25% solution, when needed every 4 hours.

Intravenous injection: 4 ml of the 25% solution, rate of injection should not exceed 0.75 ml / min.

Intravenous perfusion: 4 to 5 ml in 250 ml of 5% glucose solution or 0.9% sodium chloride solution, rate of injection should not exceed 3 ml / min.

Children: intramuscular injection, 20 – 40 mg / kg of 25% solution, diluted; dose is repeated if needed.

Magnesium sulphate solution is incompatible with alkali hydroxides (forming insoluble magnesium hydroxide), alkali carbonates (forming insoluble magnesium carbonate) and salicylates.

If you take more Sulfat magnezi than you should

If you take more Sulfat magnezi than you should or if the children have taken this medicine by mistake, contact your doctor or the nearest hospital or call the emergency service to ask for the risks and advice on actions that should be taken.

Caution is advised in patients with renal impairment as renal insufficiency may lead to magnesium intoxication.

If you forget to take Sulfat magnezi

If you forget to take one or more doses, take the next dose at the next prescribed time. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sulfat magnezi can cause side effects, although not everybody gets them. Most of the side effects are dose-related and disappear when the dose is reduced or when treatment is discontinued.

Hypersensitivity reactions may occur.

Excessive parenteral doses of magnesium salts lead to the development of hypermagnesemia, which is presented with the following signs: depression of cardiac function, circulatory collapse, cardiac arrest, central nervous system depression, muscle weakness, hypocalcemia, flushing, sweating, hypothermia, nausea, vomiting, confusion, thirst, respiratory depression, loss of tendon reflexes, coma, hypotension.

If any of these side effects gets worse or if you experience any side effects not listed in this leaflet, contact your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to the Pharmacovigilance Department of the National Agency of Drugs and Medical Devices at the email address farmakovigjilenca@akbpm.gov.al or via the website www.akbpm.gov.al/formulari-raportimi. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SULFAT MAGNEZI

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 packaging.

Store below 25°C!

Keep in the original packaging.

6. OTHER INFORMATION

What Sulfat magnezi contains

The **active substance** is Magnesium sulphate heptahydrate.

Each 10 ml ampoule contains 2500 mg magnesium sulphate heptahydrate.

The **excipient** is water for injection.

Contents of the pack

Carton box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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