



TRANSLATION BY PROTINA

Translation of the German

Package Leaflet

Information for the user

Magnesium-Diasporal® 2 mmol

48.61 mg Magnesium

Solution for injection

Active substance: Magnesium sulphate hepta hydrate

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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.
- If you do not feel better or if you feel worse, you must talk to your doctor

What is in this leaflet

1. What Magnesium-Diasporal® 2 mmol is and what it is used for
2. What you need to know before you use Magnesium-Diasporal® 2 mmol
3. How to use Magnesium-Diasporal® 2 mmol
4. Possible side effects
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1. What Magnesium-Diasporal® 2 mmol is and what it is used for

Magnesium-Diasporal® 2 mmol is a mineral supplement.

Magnesium-Diasporal® 2 mmol is used in the:

Treatment of magnesium deficiency if it causes muscular activity disorders (neuromuscular disorders, calf muscle cramps); tetanias may also be a sign of calcium deficiency. For this reason any calcium deficiency must be excluded prior to magnesium therapy by measuring the serum calcium level. Therapy with magnesium sulfate is only indicated if the magnesium serum level is below the normal values (0.8–1.1 mmol/l) and the serum calcium level is normal (2.2–2.7 mmol/l).

Treatment of pregnancy-related high blood pressure with fluid retention and protein excretion in the urine (pre-eclampsia).

Treatment of pregnancy-related seizure (eclampsia).

Tendency of preterm delivery:

Also here, treatment with magnesium sulfate may only be applied if the magnesium serum level is below the normal values.

If you do not feel better or if you feel worse after the use of this medicine, you must talk to your doctor.

2. What you need to know before you use Magnesium-Diasporal® 2 mmol

Do not use Magnesium-Diasporal® 2 mmol if:

- you have disorders of conduction on the heart that causes slow heartbeat (bradycardia)
- you suffer from myasthenia gravis (muscle weakness)
- you suffer from disorders of conduction on the heart (AV blocks)

Take special care with Magnesium-Diasporal® 2 mmol: in severe renal impairment. An adjustment of the dose to the degree of impairment is necessary.

Precautionary measures during high-dose parenteral magnesium sulfate therapy with Magnesium-Diasporal® 2 mmol:

- Knee jerk (patellar) reflexes have to be maintained. If no more triggering is possible, the dose has to be reduced.
- Respiratory rate should not drop below 16 breaths/min.
- Urinary excretion should be at a minimum of 25 ml/h, if lower, risk of magnesium oversupply exists.
- Ampoules of 10% calcium gluconate have to be kept ready as antidote.
- Intensive care measures are necessary if antidote is not sufficient.

Other medicines and Magnesium-Diasporal® 2 mmol

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

The pharmacological effect of the following active substances and preparations may be influenced by concomitant treatment with Magnesium-Diasporal® 2 mmol:

- Diuretics
- Aminoglycoside antibiotics (e.g. gentamicin, tobramycin, amphotericin B)
- Immunosuppressants (e.g. cyclosporin A)
- Cytostatics (e.g. cisplatin)
- Digitalis glycoside cause increased magnesium excretion through the kidney.

The following medicine should not be given concomitantly:

- Muscle relaxants of the curare type – they enhance the pharmacological effect of magnesium at the motor end plate.
- Barbiturates, narcotics or other hypnotics – due to the risk of respiratory depression.
- Calcium salts – they reduce the pharmacological effect of magnesium.

What you need to know when mixing Magnesium-Diasporal® 2 mmol with other solutions:

Magnesium-Diasporal® 2 mmol should not be mixed with solutions containing calcium, phosphate, tetracycline or alcohol, because of the risk of precipitation.

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 using this medicine.

There are no indications of any malformation risk when magnesium salts are given during pregnancy. Magnesium-Diasporal® 2 mmol may be used during pregnancy and breast-feeding.

However there is little documented experience of use in human early pregnancy.

If magnesium salts are administered shortly before delivery the neonate should be monitored during the first 24 to 48 hours of life for signs of toxicity (neurological depression with respiratory depression, muscle weakness, loss of reflexes). Administration of aminoglycoside antibiotics should be avoided during this period as there are indications of interactions.

Based on long-term experience, no effects on male and female fertility are anticipated.

Driving and using machines

Magnesium-Diasporal® 2 mmol has no or negligible influence on the ability to drive and use machines.

3. How to use Magnesium-Diasporal® 2 mmol

Always use 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.

Dosage

Unless otherwise prescribed by your doctor, 1 to 2 ampoules Magnesium-Diasporal® 2 mmol (equivalent to 4-8 mmol magnesium) should be administered depending on the indication and magnesium serum level.

Preeclampsia, eclampsia: 4-6 g magnesium sulfate (16-24 mmol Magnesium) i.v. in diluted form by perfusor or short infusion for 15-20 minutes.

Maintenance dose 1-2 g Magnesium sulfate/hour (4-8 mmol Magnesium/h) up to 24-48 hours post partum.

Method of administration

Magnesium-Diasporal® 2 mmol, solution for injection should be administered by intramuscular or intravenous routes.

If you have used more Magnesium-Diasporal® 2 mmol than you should:

The main symptoms and general signs of an overdose are muscle weakness, loss of deep tendon reflexes, hypotension and fall in heart rate, increase in cutaneous circulation, ECG changes, vomiting, sedation and confusion.

If the plasma magnesium concentration exceeds 2 mmol/l, the deep tendon reflexes are weakened, at approx. 5 mmol/l they are no longer present and respiratory depression occurs. At 6.0-7.5 mmol/l coma occurs and from 8 mmol/l respiratory paralysis and diastolic cardiac arrest.

Magnesium intoxication should be treated with intravenous calcium as antidote (e.g. slow i.v administration of 10 ml of 10% calcium gluconate solution)

In addition the cholinesterase blocker neostigmine should be administered as it increases the acetylcholine concentration and antagonizes the muscle relaxant effect of magnesium.

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

4. Possible side effects

Like all medicines, Magnesium-Diasporal® 2 mmol can cause side effects, although not everybody gets them. The frequency of side effects is defined in the following categories:

Very common	More than 1 in 10 users
Common	Less than 1 in 10, but more than 1 in 100 users
Uncommon	Less than 1 in 100, but more than 1 in 1.000 users
Rare	Less than 1 in 1.000, but more than 1 in 10.000 users
Very rare	Less than 1 in 10.000 users, including individual cases
Not known	Frequency cannot be estimated from the available data

Possible side effects

With intravenous administration there is a sensation of warmth of no relevance and flushing (skin redness) in uncommon cases. Too rapid parenteral administration of magnesium sulfate may induce transient undesirable effects in very rare cases, especially in vasolabile patients, in the form of nausea, headache, tingling, sweating, agitation, restlessness or drowsiness and a slowing down of cardiac and respiratory activity.

In addition parenteral administration of Magnesium-Diasporal® 2 mmol, solution for injection may lead in very rare cases to bradycardias, conduction disturbances and peripheral vasodilation.

Dose reduction, prolongation of injection time or discontinuation of the preparation generally lead to a rapid reduction in case of these undesirable effects.

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 directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: <http://www.bfarm.de>.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Magnesium-Diasporal® 2 mmol

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the folding box and on the ampoules.

Contents of the pack and other information:

What Magnesium-Diasporal® 2 mmol contains:

The active ingredient is Magnesium sulfate-heptahydrate. 1 ampoule with 5 ml contains 493,0 mg Magnesium sulfate-heptahydrate corresponding to 48,61 mg (= 2 mmol = 4 mval) magnesium-ions.

The other ingredients are water for injections.

What Magnesium Magnesium-Diasporal® 2 mmol looks like and content of the packs

Glas ampoule with colorless, clear solution.

5 ampoules per 5 ml solution for injection.

Marketing Authorisation Holder and Manufacturer

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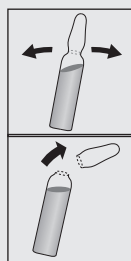
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Use of the snapoff ampoules



Color point to the top!
Let the solution in the ampoule head flow down by knocking and shaking.

Color point to the top!
Break down ampoule head.

This leaflet was last revised in 06/2013