**Package leaflet: Information for the user**

**Magnesium Sulphate 50% Inresa**
Concentrate for solution for injection or infusion

**Read all of this leaflet carefully before you start using 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. 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 serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



## 1. WHAT MAGNESIUM SULPHATE 50% INRESA IS AND WHAT IT IS USED FOR

Magnesium Sulphate 50% Inresa is a mineral supplement.
Magnesium Sulphate 50% Inresa is used in:
Pre-eclampsia, eclampsia (pregnancy-related high blood pressure disorders)

## 2. BEFORE YOU USE MAGNESIUM SULPHATE 50% INRESA

**Do not use Magnesium Sulphate 50% Inresa** in the following cases:
Pronounced bradycardia (slowed heart activity), myasthenia gravis (muscle weakness), patients with AV block (interruption of the heart's conduction system) or other heart conduction disturbances, susceptibility to struvite stones (calcium-magnesium ammonium phosphate stones), severe renal dysfunction, anuria (urine output of less than 100 mL in 24 hours) and exsiccosis (dehydration due to loss of body fluid).

**Take special care with Magnesium Sulphate 50% Inresa**
In patients with mild to moderate renal insufficiency (impaired kidney function), Magnesium Sulphate 50% Inresa should be used with special care.

**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.
Magnesium Sulphate 50% Inresa should not be used at the same time as barbiturates (sedatives), anaesthetics numbing medicines) or hypnotics (sleeping pills) due to the risk of respiratory depression (reduced breathing activity). The effect of magnesium sulphate is reduced or cancelled by combined use of IV calcium salts. Curare-type muscle relaxants (products used to relax the muscles) enhance the effect of magnesium at the neuromuscular end plate. Therefore, magnesium sulphate injections/infusions should not be used together with such muscle relaxants. Diuretics (water pills), aminoglycoside antibiotics (such as gentamicin, tobramycin, amphotericin B), immunosuppressants = agents with an inhibitory effect on the immune system (such as ciclosporin A) and cytostatics = agents used in cancer treatment (such as cisplatin) and digitalis glycosides cause increased excretion of magnesium via the kidneys. Interaction with nifedipine should also be noted, which can lead to severe hypotension (low blood pressure) and neuromuscular blockade (inhibition of impulse transmission).

**Pregnancy and breast-feeding**
There is no evidence of any risk of malformations. However, there is little documented experience with its use in humans during early pregnancy. Therefore, Magnesium Sulphate 50% Inresa should only be used during pregnancy after careful risk-benefit assessment by the treating doctor.
If magnesium sulphate is used shortly before childbirth, the newborn infant should be monitored during the first 24 - 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 time, as there is evidence of interactions.

**Driving and using machines**
Magnesium Sulphate 50% Inresa has no influence on the ability to drive and use machines.

## 3. HOW TO USE MAGNESIUM SULPHATE 50% INRESA

Magnesium Sulphate 50% Inresa is administered only by a doctor.

**Dosage**
Pre-eclampsia and eclampsia: initial dose: 4 g magnesium sulphate heptahydrate intravenously over 5 - 15 min.: maintenance dose: 1 g/hour over 24 hours (infusion)
If only a portion of the ampoule contents is used, the remaining ampoule contents must be discarded.

**Method and duration of administration:**
*For intravenous use*
Do not administer undiluted Magnesium Sulphate 50% Inresa concentrate for solution for injection or infusion into peripheral veins. For slow intravenous injection, a 20% solution (e.g. 1 ampoule + 15 mL solution for dilution) must be prepared, or a 2% solution (2 ampoules + 480 mL solution for dilution) for a continuous intravenous infusion. As a solution for dilution, a glucose 5% solution, a 5% xylitol solution or sodium chloride 0.9% solution are suitable.
It is recommended that the patient be allowed to rest for a further 10-20 minutes after injection.

*In high-dose magnesium sulphate therapy, the following must be verified:*
1. Monitoring of cardiovascular function
2. Patellar tendon reflexes (knee jerks); these must be maintained. If they can no longer be elicited, reduce the dose.
3. Breathing rate should be no less than 16 breaths/minute.
4. Urine output should be 25 mL per hour or 100 mL every 4 hours. If any lower, there is a risk of hypermagnesaemia (high blood magnesium concentrations).
5. Ampoules of calcium gluconate 10% must be kept ready as an antidote.
6. If the antidote is not sufficient in life-threatening conditions, intensive care measures must be taken.

Treatment generally lasts for 24 hours. If seizures return, it can be repeated.

**If you use more Magnesium Sulphate 50% Inresa than you should**
A dose reduction or discontinuation of the medicine leads to rapid resolution of side effects. As an immediate measure (antidote), a slow intravenous calcium injection (10-20 mL of a 10% calcium gluconate solution) can be used.

**If the amount of Magnesium Sulphate 50% Inresa administered was too low**
Dose adjustment is made by the treating doctor. If the dose administered was too low, this can be rapidly offset by appropriate adjustment of the infusion rate by the doctor.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Magnesium Sulphate 50% Inresa can cause side effects, although not everybody gets them. In the evaluation of side effects the following frequency categories are used:

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|---|---|
| **Very common** | more than 1 in 10 patients treated |
| **Common** | 1 to10 in 100 patients treated |
| **Uncommon** | 1 to10 in 1,000 patients treated |
| **Rare** | 1 to10 in 10,000 patients treated |
| **Very rare** | less than 1 in 10,000 patients treated |
| **Not known** | cannot be estimated from the available data |

Very common: flushing (redness)
Common: nausea or vomiting, muscle weakness, absent or weakened tendon reflexes, respiratory depression, reaction at the injection site (pain, burning, swelling, inflammation)
Uncommon: thirst, headache; hypotension (low blood pressure), heart palpitations, tachycardia (racing heart); dizziness, drowsiness or confusion, itching or tingling
The following may also occur: skin rash, hyperkalaemia (increased serum potassium levels), prolonged bleeding time and impaired vision.

**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 the BfArM, *Bundesinstitut für Arzneimittel und Medizinprodukte*[1], *Abt. Pharmakovigilanz*[2], Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE MAGNESIUM SULPHATE 50% INRESA

Keep out of the reach and sight of children. Do not use Magnesium Sulphate 50% Inresa after the expiry date which is stated on the ampoule and carton. The expiry date refers to the last day of that month. The medicine has a shelf life of 3 years.

**Storage conditions**
This medicinal product does not require any special storage conditions.

**Note on shelf life after opening or preparation**
The concentrate for solution for injection or infusion must be used immediately after opening the ampoule.
Do not use Magnesium Sulphate 50% Inresa, if you notice:
If you should observe cloudiness or visible particles, the solution for injection must no longer be used.

## 6. FURTHER INFORMATION

**What Magnesium Sulphate 50% Inresa contains**
The active substance is:
Magnesium sulphate heptahydrate
One 10 mL ampoule contains:
5.0 g magnesium sulphate heptahydrate equivalent to 493 mg magnesium ions, equivalent to 20.25 mmol Mg.

The other ingredients are:
Water for injections, sulphuric acid 95-98% for pH adjustment

[1] The German Federal Institute for Drugs and Medical Devices
[2] Department of Pharmacovigilance

**What Magnesium Sulphate 50% Inresa looks like and contents of the pack**
Magnesium Sulphate 50% Inresa is a clear, colourless solution.

Original packs of 50 ampoules and 50 ampoules (hospital pack), each with 10 mL concentrate for solution for injection or infusion

Original packs of 10 ampoules and 100 ampoules (hospital pack), each with 10 mL concentrate for solution for injection or infusion

**Marketing Authorisation Holder and Manufacturer**
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