

PACKAGE LEAFLET: INFORMATION FOR THE USER

Magnesium Sulfate 50 % w/v Solution for Injection/Concentrate for solution for infusion

Magnesium Sulfate Heptahydrate

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Magnesium Sulfate Injection is and what it is used for
2. What you need to know before you are given Magnesium Sulfate Injection
3. How Magnesium Sulfate Injection will be given
4. Possible side effects
5. How to store Magnesium Sulfate Injection
6. Contents of the pack and other information

1. What Magnesium Sulfate Injection is and what it is used for

Magnesium Sulfate Injection is used to treat low levels of magnesium in the blood.

It is also used for prevention (and control) of seizures in patients with severe pre-eclampsia (high blood pressure associated with pregnancy) or eclampsia (convulsions as a result of pre-eclampsia).

2. What you need to know before you are given Magnesium Sulfate Injection

You should not be given Magnesium Sulfate Injection if:

- you are allergic to Magnesium Sulfate or to any of the other ingredients in this medicine, listed in section 6 of this leaflet
- you suffer from liver or kidney failure
- you suffer from a disease of the brain associated with cirrhosis of the liver
- you have myasthenia gravis (a chronic progressive muscular weakness disease)
- you suffer from heart disease

Warnings and precautions

Talk to your doctor, pharmacist or nurse before receiving Magnesium Sulfate Injection if you:

- you suffer from any liver or kidney problems

Other medicines and Magnesium Sulfate Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Medicines which may interact with Magnesium Sulfate Injection include:

- CNS depressants (medicines that act on the central nervous system to cause drowsiness)
- digitalis (a medicine used to treat heart problems)
- muscle relaxants e.g. tubocurarine
- nifedipine (a medicine used to treat high blood pressure)

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 taking this medicine.

Driving and using machines

There are no known effects of Magnesium Sulfate Injection on driving and using machines. Please speak to your doctor before driving or operating machinery.

3. How Magnesium Sulfate Injection will be given

Your doctor will give Magnesium Sulfate Injection to you into a vein (intravenous) or into the muscle (intramuscular) either by injection or infusion (drip). Your doctor will decide how much Magnesium Sulfate should be given to you.

For the treatment of low magnesium levels:

You will be given up to 40g by slow intravenous infusion (drip) over a period of up to 5 days.

To prevent fits associated with eclampsia:

After an initial intravenous dose you will be monitored for 24 hours and then you may be given either an intravenous infusion (drip) or regular intramuscular injections.

Intramuscular Maintenance Regimen

A loading dose of 4g MgSO₄ IV (usually in 20% solution) over 5min (minimum, preferably 10-15 min) is followed immediately by 5g MgSO₄ (approx. 20mmol Mg²⁺) (usually in 50% solution) as a deep IM injection into the upper outer quadrant of each buttock.

Maintenance therapy is a further 5g MgSO₄ IM every 4h, continued for 24h after the last fit (provided the respiratory rate is >16/min, urine output >25ml/h, and knee jerks are present).

Intravenous Maintenance Regimen

A loading dose of 4g MgSO₄ IV (or in some cases 5g MgSO₄ IV, as described above, is followed by an infusion of 1g/h continued for 24h after the last fit.

Recurrent Convulsions: In both the IM and IV regimens, if convulsions recur, a further 2-4g MgSO₄ (depending on the woman's weight, 2g MgSO₄ if less than 70Kg is given IV over 5 min.

Elderly

No special recommendation except in patients with kidney problems.

Patients with kidney problems will be given a reduced dose.

If you are given too much or too little Magnesium Sulfate Injection

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too much or too little, however, tell your doctor if you have any concerns.

Continued overleaf

4. Possible side effects

Like all medicines, Magnesium Sulfate Injection can cause side effects, although not everybody gets them.

Serious side effects which are very rare are:

- Heart attack (shortness of breath, chest pain, feeling faint and/or dizzy)
- Coma

Tell your doctor, pharmacist or nurse immediately if you think you have symptoms related to the above.

The most common side effects are:

- Respiratory depression (slow or shallow breathing) and abnormal heartbeats
- Nausea (feeling sick) and/or vomiting
- Lowering of blood pressure
- Sweating and high temperature
- Thirst
- Confusion
- Drowsiness
- Muscle weakness

Tell your doctor, pharmacist or nurse immediately if you think you have any of the above side effects, or other problems.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How to store Magnesium Sulfate Injection

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

This Magnesium Sulfate Injection should not be used after the expiry date which is printed on the carton and ampoule label after EXP. The doctor or nurse will check that the expiry date on the label has not passed before administering the injection to you. The expiry date refers to the last day of that month.

Do not store above 25°C.

The ampoule containing the injection will only be used for you and if any injection is left over the doctor/nurse will dispose of it.

6. Contents of the pack and other information

What Magnesium Sulfate Injection contains

The active substance is Magnesium Sulfate Heptahydrate
2ml contains 1g Magnesium Sulfate Heptahydrate (4mmol Mg²⁺)
5ml contains 2.5g Magnesium Sulfate Heptahydrate (10mmol Mg²⁺)
10ml contains 5g Magnesium Sulfate Heptahydrate (20mmol Mg²⁺)
The other ingredients are water for injection, hydrochloric acid and sodium hydroxide.

What Magnesium Sulfate Injection looks like and contents of the pack

Magnesium Sulfate sterile solution for injection/ concentrate for solution for infusion is a clear solution supplied in 2ml, 5ml and 10ml glass ampoules. 10 ampoules are packed in each carton.

Marketing Authorisation Holder

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Version E:		
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