

Magnesium Sulfate 50% w/v Solution for Injection

Magnesium Sulfate Heptahydrate
5g/10ml, 2.5g/5ml and 1g/2ml

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 of the side effects, talk to your doctor, 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 where it is not possible for the medicine to be taken by mouth.

It may also be used to prevent seizures (fits) caused by a serious complication of pregnancy known as eclampsia.

It is used in the treatment of acute hypomagnesaemia.

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, its salts or any of the other ingredients of this medicine listed in section 6.
- you suffer from severe kidney failure.

Warnings and Precautions

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

- suffer from any kidney problem.
- suffer from disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs known as myasthenia gravis.

During treatment

Your blood calcium levels will be routinely monitored whilst taking Magnesium Sulfate.

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:

- Digitalis glycosides e.g. digoxin (a medicine used to treat heart problems)
- Barbiturates (e.g. amobarbital)

- Opioids (e.g. morphine)
- Hypnotics (e.g. nitrazepam)
- Muscle relaxants e.g. tubocurarine
- Calcium channel blockers e.g. nifedipine or nimodipine (medicines used to treat high blood pressure) which could result in calcium ion imbalance causing abnormal muscle function.
- Aminoglycoside antibacterials (such as Streptomycin)

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. Tell your doctor if you are pregnant or trying to become pregnant. Magnesium Sulfate Injection will only be given to you if your doctor considers the benefit of treatment outweighs the risk to the developing baby. Low blood calcium levels and effects on the bones, such a reduced bone density, have been reported in babies whose mothers were given magnesium sulphate continuously for more than 5-7 days during pregnancy.

It is not advisable to administer magnesium sulfate during pregnancy or breast-feeding unless considered essential, and it must be administered under medical supervision. If used in pregnant women the baby's heart rate will be monitored and will not be used within 2 hours of delivery.

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) (in glucose 5%) 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.

Continued overleaf

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.

Renal Failure:

Doses must be reduced in renal failure. Caution must be observed to prevent exceeding the renal excretory capacity. The dosage should not exceed 20g in 48 hours (100ml of a 20% solution or 80mmol of magnesium ions).

Elderly

No special recommendation except in patients with kidney problems.

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.

4.Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or nurse immediately if you get any of the following:

- Allergic reactions such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- High blood sugars causing severe dehydration (Hyperosmolar dehydration).
- Heart attack (shortness of breath, chest pain, feeling faint and/or dizzy)
- coma

Other side effects:

- feeling or being sick
- flushing of the skin
- feeling thirsty
- loss/slowed reflexes
- temporarily low blood pressure
- drowsiness
- confusion
- muscle weakness
- slowed breathing
- irregular or slow heartbeat
- Problems with the balance of salts and water in the blood. This may lead to thirst (which may be severe), dry mouth, tiredness, restlessness and muscle weakness. There have been isolated reports of low blood calcium levels in mothers and their new-born babies following prolonged use and high doses of magnesium sulphate during pregnancy.
- low phosphate levels in the blood (Hypophosphataemia)
- double vision
- slurred speech
- sweating
- dizziness
- headache
- pain and burning at the site of injection following IV/IM injection
- risk of itching and tingling
- rapid heartbeat

Reporting of side effects

If you or your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You

can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5.How to store Magnesium Sulfate Injection

Keep 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. After opening the ampoule, the solution for injection must be used immediately. 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.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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