

Package leaflet: Information for the patient

Magnesium Sulfate 20% w/v solution for infusion.

Magnesium Sulfate Ph.Eur.

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any 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 is and what it is used for
2. What you need to know before you use Magnesium Sulfate
3. How to use Magnesium Sulfate
4. Possible side effects
5. How to store Magnesium Sulfate
6. Contents of the pack and other information

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

Magnesium Sulfate solution for infusion is used to treat low levels of magnesium in the blood.

Magnesium Sulfate solution for infusion is used to treat seizures caused by a serious complication of pregnancy known as eclampsia.

2. What you need to know before you use Magnesium Sulfate

Do not use Magnesium Sulfate:

- if you are allergic to magnesium sulfate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from liver failure.
- if you suffer from kidney failure.
- if you have heart block.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Magnesium Sulfate:

- if you suffer from liver or kidney failure
- if you suffer from a respiratory disease
- if you suffer from muscle weakness (myasthenia gravis)

Other medicines and Magnesium Sulfate

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

Medicines which may interact with Magnesium Sulfate include:

- muscle relaxants
- nifedipine (used to treat high blood pressure)
- digitalis (used to treat heart problems)
- central nervous system depres-

sants (medicines which act on the central nervous system to cause drowsiness)

- aminoglycoside antibacterials (used to treat infections)
- intravenously administered calcium.

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.

It is not advisable to administer magnesium sulfate during pregnancy or breastfeeding unless considered essential, and it must be administered under medical supervision. If used in pregnant women the baby's heart rate should be monitored and use within 2 hours of delivery should be avoided. If used repeatedly or for longer periods during pregnancy, monitoring of mineral levels and skeletal side effects in the newborn baby should be considered.

3. How to use Magnesium Sulfate

Your doctor will give Magnesium Sulfate to you as an infusion (drip) into a vein. Your doctor will decide how much Magnesium Sulfate should be given to you.

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The following information is intended for healthcare professionals only:

Posology

Dosage should be tailored according to the individual patient's needs and responses. Plasma magnesium concentrations should be measured to determine the rate and duration of infusion and should be monitored throughout therapy.

Concentrations of magnesium sulfate injection

Magnesium sulfate heptahydrate concentration (percentage w/v)	Magnesium ions equivalence (approximate) (millimoles magnesium (Mg ²⁺) per ml)	Magnesium sulfate heptahydrate concentration (mg/ml) equivalence
20% w/v	0.8 mmol/ml	200mg/ml

Treatment of magnesium deficiency in

hypomagnesaemia

Up to 40 g or 160 mmols of magnesium ions (200ml of a 20% solution) by slow intravenous infusion (in glucose 5%) over up to 5 days, may be required to replace the deficit (allowing for urinary losses).

Elderly

No special recommendation. Use with caution due to risk of renal impairment in this age group, see below.

Renal impairment

Doses must be reduced in renal impairment. 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 80mmols of magnesium ions).

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The recommended dose for magnesium deficiency is up to 200 ml of a 20% solution by slow intravenous infusion over up to 5 days.

The recommended dose for prevention of recurrent seizures in eclampsia is a loading dose of 20ml of a 20% solution, followed by an infusion of 5ml of a 20% solution/hour, continued for 24 hours after the last fit.

If you are given more Magnesium Sulfate than you should have

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.

The following side effects have been observed with the use of Magnesium Sulfate:

- Hypersensitivity reactions such as itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips.

Excessive administration of magnesium leads to the development of symptoms of hypermagnesaemia which may include:

- Electrolyte/fluid abnormalities
- Low levels of calcium in your blood (which may cause pins and needles or twitching muscles) with use of high doses in the pregnant mother and baby
- Slow or shallow breathing

- Nausea, vomiting, drowsiness and confusion
- Coma
- Slurred speech, double vision
- Irregular heartbeat, heart attack
- Electrocardiogram (ECG) changes slowed heart rate.
- Flushing of the skin and low blood pressure due to dilation of blood vessels.
- Loss of tendon reflexes, muscle weakness
- Thirst

Reporting of side effects

If you get 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, Website: 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

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 label and carton after EXP. The expiry date refers to the last day of that month.

The product must be used immediately after the opening of the container and the storage of opened ampoules should be avoided.

6. Contents of the pack and other information

What Magnesium Sulfate contains

- The active substance is magnesium sulfate heptahydrate.
- The other excipient is water for injections

What Magnesium Sulfate looks like and contents of the pack

Magnesium Sulfate is a clear and colourless solution, provided in transparent and colourless glass ampoule type I. The ampoules are inserted into polypropylene blisters and packed in carton boxes. Each carton box contains 10 ampoules of 10 ml or 5 ampoules of 20 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Synchrony Pharma Ltd.
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Manufacturer

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Prevention of recurrent seizures in eclampsia

A loading dose of 4g (16 mmols) of magnesium ions IV (20ml of a 20% solution) or in some cases 5g (20 mmols) of magnesium ions IV (25ml of a 20% solution), given over 5-15 minutes, is followed by an infusion of 1g (4mmols)/h (5ml of a 20% solution) continued for 24h after the last fit.

Recurrent Convulsions: If convulsions recur, a further 2-4g (8-16 mmols) of magnesium ions (10-20ml of a 20% solution, depending on the woman's weight, 2g (8 mmols) if less than 70Kg) is given IV over 5 min.

Appropriate reductions in dosage should be made for patients with renal impairment; a suggested dose reduction in severe renal impairment is a maximum of 20g (80 mmols of magnesium ions) over 48 hours.

Paediatric population

No special recommendation.

Method of administration

Intravenous infusion.

Magnesium sulfate can be diluted with Glucose 5% and Sodium chloride 0.9% solutions.

Disposal

No special requirements.