

Package leaflet: Information for the user
Magnesium Sulfate 20% w/v Solution for Injection or Infusion
Magnesium sulfate heptahydrate

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 Solution for Injection or Infusion is and what it is used for
2. What you need to know before you use Magnesium Sulfate Solution for Injection or Infusion
3. How to use Magnesium Sulfate Solution for Injection or Infusion
4. Possible side effects
5. How to store Magnesium Sulfate Solution for Injection or Infusion
6. Contents of the pack and other information

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

The name of your medicine is Magnesium Sulfate 20% w/v Solution for Injection or Infusion. This will be referred to as Magnesium Sulfate Solution for Injection or Infusion throughout this leaflet.

This medicine is an electrolyte solution and contains the active substance, magnesium sulfate heptahydrate, which plays a number of important roles in the body, including regulation of the nervous and blood systems.

Magnesium Sulfate Solution for Injection or Infusion is used to:

- treat low levels of magnesium in the blood
- prevent and control further seizures (fits) in patients with eclampsia (fits during pregnancy)
- prevent and control seizures (fits) in severe pre-eclampsia (high blood pressure associated with pregnancy).

2. What you need to know before you use Magnesium Sulfate Solution for Injection or Infusion

Do not use Magnesium Sulfate Solution for Injection or Infusion if you:

- are allergic to magnesium sulfate or any other ingredients of this medicine (listed in section 6)
- have or had kidney failure
- have or had liver problems and failure
- have or had heart problems

Talk to your doctor if you are concerned about any of the above.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before being given Magnesium Sulfate Solution for Injection or Infusion if you:

- have or had liver disease or have kidney disease as your doctor may need to adjust your dose
- have any breathing difficulties or lung diseases
- have a disease causing muscle weakness and fatigue (myasthenia gravis)

Children and adolescents

There is no relevant use of Magnesium Sulfate Solution for Injection or Infusion in children for the treatment of hypomagnesaemia. Magnesium sulfate can be used with caution in female adolescents with pre-eclampsia and eclampsia.

Other medicines and Magnesium Sulfate Solution for Injection or Infusion

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This includes medicines bought without a prescription, including herbal medicines. In particular, tell your doctor if you are using any of the following medicines:

- Muscle relaxants, for example rocuronium or vecuronium
- Calcium-channel blockers, e.g. nifedipine, lercanidipine or amlodipine, may result in abnormal muscle function and low blood pressure
- Central nervous system depressants (medicines which act on the brain to cause drowsiness), such as drugs used in anxiety called benzodiazepines (e.g. diazepam) or medicines to help with sleeping called hypnotics (e.g. zopiclone)
- Aminoglycoside antibacterial (used to treat infections), for example gentamicin and tobramycin
- Heart medicines such as digitalis glycosides and digoxin
- Intravenously administered calcium
- Diuretic agents e.g. furosemide
- Antacids and laxatives
- Vasodilator agents such as non-selective alpha-adrenergic blockers e.g. phentolamine
- Cisplatin, amphotericin B and ciclosporin.

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, pharmacist or nurse for advice before using this medicine. Tell your doctor if you are pregnant or trying to become pregnant.

Magnesium Sulfate Solution for Injection or Infusion is used to treat serious complications in pregnancy. Your doctor will only give you Magnesium Sulfate Solution for Injection or Infusion if the benefit of treatment outweighs the risk to you and the developing baby. Low blood calcium levels and effects on the bones, such as reduced bone density, have been reported in babies whose mothers were given magnesium sulfate continuously for more than 5-7 days during pregnancy. If used repeatedly or for longer periods during pregnancy, monitoring of mineral levels and skeletal side effects in the newborn baby should be considered.

Driving and using machines

Do not drive or operate machines if you feel dizzy, tired, sleepy, have vertigo or blurred vision after taking this medicine.

3. How to use Magnesium Sulfate Solution for Injection or Infusion

Your doctor will decide what dose of this medicine you should be given. Check with your doctor, pharmacist or nurse if you are not sure. The dose will depend on the individual needs and the response to treatment. Your blood levels will be monitored during treatment.

Treatment of magnesium deficiency

The recommended dose for the treatment of magnesium deficiency is up to 200 mL of a 20% w/v solution by slow intravenous infusion given over a period of up to 5 days.

Prevention and control of seizures in severe pre-eclampsia

The recommended dose is an initial dose of 20 mL of a 20% w/v solution given slowly over a period of 5-15 minutes, followed by an infusion of 5 mL of a 20% w/v solution per hour for 24 hours after the last seizure.



Information for healthcare professionals only
(as stated on the Summary of Product Characteristics)

The following information is intended for healthcare professionals only:

Therapeutic indications

- Treatment of magnesium deficiency in hypomagnesaemia.
- Prevention and control of seizures in severe pre-eclampsia.
- Prevention and control of recurrent seizures in eclampsia.

Posology and Method of Administration

Posology

Dosages should be adjusted according to the patient's needs, responses and weight. Plasma magnesium levels should also be monitored during treatment to determine the rate and duration of infusion.

Close monitoring for ECG changes is required (see section 4.8 of the SmPC). The infusion rate should be reduced or stopped if the patient develops signs of changes to cardiac condition (ECG changes).

Treatment of magnesium deficiency in hypomagnesaemia:

Treatment should be given via an infusion rate of 1 g magnesium sulfate (5 mL of a 20% w/v solution equivalent to 4mmol of magnesium ions) per hour is recommended, with a maximum rate of 2 g magnesium sulfate (10 mL of a 20% w/v solution approximately 8 mmol magnesium ions) per hour (not exceeding 28 g in 24 hours).

Higher infusion rates may be given in the management of emergencies.

Up to 40 g (200 mL of a 20% w/v solution equivalent to 160 mmol of magnesium ions) by slow intravenous infusion (in glucose 5% w/v) given over a period of up to 5 days, may be required to replace the deficit (allowing for urinary losses).

In exceptional circumstances and under close supervision a higher dose within the range of 2 g to 5 g of magnesium sulfate (10 mL to 25 mL of a 20% w/v solution equivalent to 8 to 20 mmol of magnesium ions) in at least 100 mL of Glucose 5% w/v or Sodium Chloride 0.9% w/v over 6 hours may be considered.

Prevention and control of seizures in severe pre-eclampsia:

An intravenous loading dose of typically 4 g (20 mL of a 20% w/v solution equivalent to 16 mmol of magnesium ions) given slowly over a period of 5-15 minutes is followed by an infusion of 1 g (5 mL of a 20% w/v solution equivalent to 4 mmol of magnesium ions) per hour for 24 hours after the last seizure.

Prevention and control of recurrent seizures in eclampsia:

An intravenous loading dose of typically 4 g (20 mL of a 20% w/v solution equivalent to 16 mmol of magnesium ions) given slowly over a period of 5-15 minutes is followed by an infusion of 1 g (5 mL of a 20% w/v solution equivalent to 4 mmol of magnesium ions) per hour continued for 24 hours after the last seizure or delivery postpartum (whichever is later).

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Prevention and control of further seizures in eclampsia

The recommended dose is an initial dose of 20 mL of a 20% w/v solution given slowly over a period of 5-15 minutes, followed by an infusion of 5 mL of a 20% w/v solution per hour, continued for 24 hours after the last seizure.

If seizures recur, a further 10-20 mL of magnesium can be given over 5 minutes via IV route.

You may be given a different dose by your doctor if you have problems with your kidneys or liver.

If more of Magnesium Sulfate Solution for Injection or Infusion is given than should be

As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much of this medicine, however, tell your doctor as soon as possible if you have any concerns.

In the unlikely event of an overdose your doctor will monitor your side effects. If you are a medical practitioner administering this medicine an overdose may be reversed with calcium salts which should be administered slowly intravenously in a dose equivalent to 2.5 to 5 mmol of calcium (please refer to the Summary of Product Characteristics).

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

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, for example an itchy rash, swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing) or a feeling that you are going to faint.

Excessive administration of magnesium leads to the development of symptoms of hypermagnesaemia. This can include the side effects as listed below.

Serious side effects which are very rare are:

- heart attack (shortness of breath, chest pain, feeling faint and/or dizzy)
- coma
- hypermagnesaemia

The other side effects are:

- problems with the balance of salts and water in the blood. This may lead to thirst (which may be severe)
- flushing of the skin
- tiredness
- skin rashes
- loss of knee jerk reflex
- muscle weakness
- abnormal heartbeats
- shallow or slow breathing
- feeling or being sick
- sweating
- high temperature
- headache, dizziness, confusion
- double vision, blurred vision and drooping eyelid
- slurred speech
- pain, burning, inflammation and bruising at injection site

There have been isolated reports of low blood calcium levels in mothers and their newborn babies following prolonged use and high doses of magnesium sulfate during pregnancy.

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 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 Solution for Injection or Infusion

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 vial and carton.

The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions.

This medicine must be used immediately after opening of the container and the storage of open vials avoided.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Magnesium Sulfate Solution for Injection or Infusion contains

The active substance is magnesium sulfate heptahydrate at a strength of 200 g per litre (approximately 0.8 mmol magnesium per mL).

The other ingredients are sulfuric acid and Water for Injections.

What Magnesium Sulfate Solution for Injection or Infusion looks like and contents of the pack

This medicine is a clear and colourless solution.

This medicine is available in 20 mL and 50 mL vials, packed into cartons containing 1 vial or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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If seizures recur, a further 2-4 g (10-20 mL of a 20% w/v solution equivalent to 8-16 mmol of magnesium ions), depending on the woman's weight, 2 g (8 mmol) if less than 70 kg, is given intravenously over 5 minutes.

Renal impairment

Appropriate reductions in dosage should be made for patients with renal impairment due to increased risk of toxicity (see section 4.4 of the SmPC). Caution must be observed to prevent exceeding the renal capacity. The dosage should not exceed 20 g in 48 hours (100 mL of a 20% w/v Solution equivalent to 80 mmol of magnesium ions).

Elderly

There are no special recommendations for use in the elderly but caution needs to be exercised in this population due to the risk of renal impairment (see section 4.4. of the SmPC).

Paediatric Population

There is no relevant use of Magnesium Sulfate 20% w/v Solution for Injection or Infusion in the paediatric population for the indication of hypomagnesaemia.

Limited studies of the use of the magnesium sulfate in adolescent females with pre-eclampsia and eclampsia show there are no contraindications, however it should be used with caution.

Method of administration

For intravenous administration.

For peripheral administration a concentration of magnesium sulfate 5% w/v (diluted with Glucose 5% w/v or Sodium Chloride 0.9% w/v) is recommended. For example, dilute 25 mL of Magnesium Sulfate 20% w/v to 100 mL using Glucose 5% w/v or Sodium Chloride 0.9% w/v. The resultant admixture contains 20 mmol (5g) of magnesium ions per 100 mL.

For instructions on dilution of the medicinal product before administration see section 6.6 of the SmPC.

Incompatibilities

This medicinal product must not be mixed with other medicinal products, with the exception of dilution with Glucose 5% w/v or Sodium Chloride 0.9% w/v solutions.

Shelf life

24 months

Chemical and physical in use-stability has been demonstrated for 24 hours at a maximum of 25°C. From a microbiological point of view, the product should be used immediately.

If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.