

Package Leaflet: Information for the user
Magnesium Sulfate 50% 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 50% w/v Solution for Injection or Infusion is and what it is used for**
- 2. What you need to know before you are given Magnesium Sulfate 50% w/v Solution for Injection or Infusion**
- 3. How Magnesium Sulfate 50% w/v Solution for Injection or Infusion is given**
- 4. Possible side effects**
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- 6. Contents of the pack and other information**

1. What Magnesium Sulfate 50% w/v Solution for Injection or Infusion is and what it is used for

Magnesium Sulfate 50% w/v Solution for Injection or Infusion contains magnesium (as magnesium sulfate heptahydrate). Magnesium sulfate heptahydrate (hereafter referred to as magnesium sulfate) is a magnesium salt. It is used:

In adults, adolescents and children

- to treat magnesium deficiency (shortage);
- to prevent and treat low levels of magnesium in the blood in patients receiving total parenteral nutrition (nutrients that are infused into the bloodstream).

In pregnant women

- to control and prevent seizures in severe pre-eclampsia (serious complication of pregnancy characterized by high blood pressure and protein in your urine);
- to control and prevent recurrent seizures in eclampsia (convulsions as a result of pre-eclampsia).

2. What you need to know before you are given Magnesium Sulfate 50% w/v Solution for Injection or Infusion

You should not be given Magnesium Sulfate 50% w/v Solution for Injection or Infusion

- If you are allergic to magnesium sulfate, its salts or any of the other ingredients of this medicine (listed in section 6);
- you have liver failure or condition known as ‘hepatic encephalopathy’ (impaired brain function due to liver disease);
- you have kidney failure or severe kidney problems, or you cannot make or pass urine;
- you have heart problems or a disease causing muscle weakness and fatigue called ‘myasthenia gravis’ (in these cases you should not be given magnesium sulfate by injection).

If any of the above apply to you please tell your doctor or nurse before you are given Magnesium Sulfate 50% w/v Solution for Injection or Infusion.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before you are given Magnesium Sulfate 50% w/v Solution for Injection or Infusion:

- if you have kidney problems (you will need reduced dose);
- if you have liver problems.

Tell your doctor or nurse if flushing and sweating occurs.

Your magnesium and calcium blood levels will be monitored during treatment.

Your reflexes, breathing and urine output will also be checked while receiving magnesium sulfate.

Other medicines and Magnesium Sulfate 50% w/v Solution for Injection or Infusion

Tell your doctor or pharmacist or nurse if you are using, have recently used or might use any other medicines. Medicines which may interact with magnesium sulfate include:

- Muscle relaxants e.g. vecuronium
- Nifedipine (used to treat high blood pressure or chest pain)
- Calcium channel blockers (medicines to treat high blood pressure and chest pain)
- Diuretics (medicines that increase the passage of urine) such as thiazides and furosemide
- Calcium salts
- Digitalis glycosides e.g. digoxin (a medicine used to treat heart problems)
- Aminoglycoside antibacterial agents (medicines used to treat bacterial infections)
- Barbiturates (medicines for treating anxiety, insomnia)
- Opioids (medicines for treating chronic pain) such as morphine
- Hypnotics (medicines for sleep disorders).

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine. Magnesium Sulfate 50% w/v Solution for Injection or Infusion may be used to treat the fits associated with pre-eclampsia and eclampsia, a serious complication of pregnancy.

If you are pregnant and you are given Magnesium Sulfate 50% w/v Solution for Injection or Infusion, your baby’s heart rate will be thoroughly monitored and use within 2 hours of delivery will be avoided. Magnesium sulfate can cause foetal skeletal adverse effects when given continuously for more than 5 to 7 days to pregnant women. In case of prolonged or repeated use of magnesium sulfate during pregnancy, your baby will be monitored for abnormal calcium or magnesium levels and skeletal adverse effects. You will not receive Magnesium Sulfate 50% w/v Solution for Injection or Infusion during pregnancy or breast-feeding unless considered essential by your doctor, and it will be given to you under medical supervision. Your doctor will assess that the potential benefits outweigh the risks before giving this medicine to you.

Magnesium sulfate has no effects on fertility.

Driving and using machines

Magnesium Sulfate 50% w/v Solution for Injection or Infusion is unlikely to affect the ability to drive and use machines. However, some people may feel dizzy or drowsy after receiving Magnesium Sulfate injection. If you experience these side effects, do not to drive or use machines.

3. How Magnesium Sulfate 50% w/v Solution for Injection or Infusion is given

This medicine will be given to you as an injection or infusion into a vein (after being diluted) or as an injection into a muscle.

continued overleaf



**Additional information for Healthcare Professionals
(as stated on the Summary of Product Characteristics)**

The following information is intended for healthcare professionals only:

Magnesium Sulfate 50% w/v Solution for Injection or Infusion

Magnesium sulfate heptahydrate

Route and method of administration

For intravenous injection or infusion or intramuscular injection.

Intravenous (IV):

DILUTE BEFORE IV USE

For intravenous administration, a concentration of 20% or less should be used; the rate of injection not exceeding 1.5 ml/minute of a 10% solution or its equivalent.

Intramuscular (IM):

Intramuscular injection is painful (avoid if possible).

Adults: For deep intramuscular injection in adults, undiluted Magnesium sulfate 50% w/v solution is used.

Children: The solution should be diluted to a 20% or less concentration prior to deep intramuscular injection in children.

Note: Do not administer into muscles which are emaciated or atrophied. Do not use an injection site that has evidence of infection or injury. Dorsogluteal muscle and sciatic nerve should be avoided. If the total dose to be administered exceeds 5 ml, the injection volume should be divided between more than one deep muscular injection site. Use caution in older or thin patients who may only tolerate up to 2 ml in a single injection. If repeating an IM dose, rotate injection sites to avoid injury or discomfort to the muscles.

For instructions on dilution before administration, see ‘Instructions for use, disposal and other handling’ below.

Posology

Magnesium sulfate heptahydrate 50% w/v (2 mmol Mg²⁺ in 1 ml).

Magnesium sulfate heptahydrate 1 g = 98.6 mg or 8.1 mEq or approximately 4 mmol magnesium (Mg²⁺).

The concentrations of magnesium ions (Mg²⁺) in millimoles are given as approximate values.

Therapeutic levels are reached almost immediately with appropriate intravenous doses and within 60 minutes following intramuscular injection.

Adults

Hypomagnesaemia

The dose is strictly individual. As a general guideline, 8-12 g of magnesium sulfate (32-48 mmol Mg²⁺) can be administered in the first 24 hours followed by 4-6 g (16-24 mmol Mg²⁺) per day for 3 or 4 days, to replete body stores. Maximum infusion rates should not exceed 2 g/hour (8 mmol Mg²⁺/hour). The aim should be to maintain serum magnesium concentrations above 0.4 mmol/l.

Alternatively, 2-4 ml of Magnesium Sulfate 50% w/v solution (4-8 mmol Mg²⁺) can be injected intramuscularly every 6 hours for 24 hours (4 doses in total).

Severe pre-eclampsia or eclampsia

Intravenously an initial loading dose of 4-5 g of magnesium sulfate (16-20 mmol Mg²⁺) diluted to an appropriate volume may be infused. This is followed by a maintenance regimen of either an intravenous (IV) infusion or regular intramuscular (IM) injections as follows:

- **IV maintenance regimen:** the loading dose is followed by an IV infusion of 1-2 g/hour (4-8 mmol Mg²⁺/hour);
- **IM maintenance regimen:** the loading dose is followed by regular IM injections of 4-5 g of magnesium sulfate (8-10 ml of undiluted Magnesium Sulfate 50% w/v solution corresponding to 16-20 mmol Mg²⁺) into alternate buttocks every 4 hours, depending on the continuing presence of the patellar reflex and adequate respiratory function. Therapy should continue until paroxysms cease.

Paediatric population

For deep intramuscular injection in children, Magnesium Sulfate 50% w/v solution should be diluted to a 20% or less concentration prior to use.

Your doctor will decide how much magnesium sulfate should be given to you. The usual doses are given below.

Adults

For magnesium deficiency, you will be given

8-12 g of magnesium sulfate in the first 24 hours followed by 4-6 g/day for 3 or 4 days, to replete body stores.

Alternatively, 2-4 ml of undiluted Magnesium Sulfate 50% w/v solution can be injected into a muscle (may be painful) every 6 hours for 24 hours (4 doses in total).

For the control and prevention of seizures in severe pre-eclampsia or eclampsia:

An initial loading dose of 4-5 g magnesium sulfate diluted to an appropriate volume will be given into your vein. It will be followed by either an infusion into a vein of 1-2 g/hour or regular injections into a muscle of undiluted Magnesium Sulfate 50% w/v solution, until seizures cease.

Patients with kidney problems

Patients with kidney problems will be given a reduced dose.

Patients with liver problems

There are no special dosage instructions.

Elderly

Caution should be observed as kidney and/or liver disorders and side effects are more likely in this age group.

Use in children

In children, Magnesium Sulfate 50% w/v solution, appropriately diluted prior to use, may be given as an injection into a muscle.

If you are given too much Magnesium Sulfate 50% w/v Solution for Injection or Infusion

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much. However, tell your doctor or nurse if you have any concerns.

If you forget to be given Magnesium Sulfate 50% w/v Solution for Injection or Infusion

It is unlikely that you will miss a dose as your doctor or nurse will be giving it to you. You should not receive a double dose if you have missed one. Ask your doctor or nurse when you should have the next dose.

4. Possible side effects

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

Frequency not known (cannot be estimated from the available data)

- Electrolyte/fluid abnormalities
- Breathing difficulties
- Feeling or being sick
- Drowsiness
- Confusion
- Slurred speech
- Double vision
- Loss of tendon reflexes
- Irregular heartbeat
- Cardiac arrest
- Electrocardiogram (ECG) abnormalities
- Slowed heart rate
- Flushing of the skin and low blood pressure due to dilation of blood vessels
- Muscle weakness
- Thirst
- Coma

Low blood calcium levels in pregnant women and their developing babies have been reported extremely rarely with high doses of magnesium sulfate (see 'Pregnancy, breast-feeding and fertility').

Hypersensitivity reactions cannot be ruled out.

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: 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 50% w/v Solution for Injection or Infusion

- Keep this medicine out of the sight and reach of children.
- Do not freeze.
- Do not use this medicine after the expiry date which is stated on the ampoule, vial and carton. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any visible signs of deterioration (e.g. particles).
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Magnesium Sulfate 50% w/v Solution for Injection or Infusion contains:

- The active substance is Magnesium Sulfate Heptahydrate
 - Each 2 ml ampoule contains 4 mmol Mg²⁺ (equivalent to 1 g magnesium sulfate heptahydrate).
 - Each 5 ml ampoule contains 10 mmol Mg²⁺ (equivalent to 2.5 g magnesium sulfate heptahydrate).
 - Each 10 ml ampoule contains 20 mmol Mg²⁺ (equivalent to 5 g magnesium sulfate heptahydrate).
 - Each 20 ml vial contains 40 mmol Mg²⁺ (equivalent to 10 g magnesium sulfate heptahydrate).
 - Each 50 ml vial contains 100 mmol Mg²⁺ (equivalent to 25 g magnesium sulfate heptahydrate).
 - Each 100 ml vial contains 200 mmol Mg²⁺ (equivalent to 50 g magnesium sulfate heptahydrate).
- The other ingredients are Sulfuric Acid (for pH adjustment) and Water for Injections.

What Magnesium Sulfate 50% w/v 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 2mL, 5mL and 10mL ampoules, and 20mL, 50mL and 100mL vials. The medicine is packed into cartons containing 10 ampoules, 1 vial or 10 vials. Both pack sizes of vials may not be available at the same time.

Marketing Authorisation Holder and Manufacturer:

Torbay Pharmaceuticals Limited,
Wilkins Drive,
Paignton,
Devon,
TQ4 7FG, UK
+44 (1803) 664707
med.info@torbaypharma.com

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Renal insufficiency

Patients with renal insufficiency should receive 25-50% of the initial dose recommended for patients with normal kidney function. ECG monitoring is recommended with high doses and in the elderly.

Hepatic impairment

No special dosage instructions are available.

Elderly

Parenteral magnesium sulfate should be used with caution in the elderly because renal and/or hepatic disorders are more frequent in this age group and the tolerance to adverse effects may be lower.

Instructions for use, disposal and other handling

For single use only. Discard any unused contents. Can be diluted with 0.9% sodium chloride or 5% glucose solutions.

This medicinal product must not be mixed with other medicinal products except those mentioned above.

An antidote of injectable calcium gluconate solution should be immediately available.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Shelf life

Shelf life after first opening: The medicinal product should be used immediately after opening.

Shelf life after dilution: Chemical and physical in-use stability has been demonstrated for both 50% and diluted (20% w/v) solutions when stored protected from light in 10mL polypropylene syringes in the refrigerator and at 25°C for 28 days.

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 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Overdose

Symptoms

Intravenous magnesium infusions can result in hypermagnesaemia even in the presence of normal kidney function. Clinical signs of overdose will be those of hypermagnesaemia. Patients with renal failure and metabolic derangements develop toxicity at lower doses. Disappearance of the deep tendon reflex is a useful clinical sign to detect the onset of magnesium intoxication. Magnesium intoxication is manifested by a sharp drop in blood pressure and respiratory paralysis. The potential symptoms of hypermagnesaemia are as follows:

Magnesium levels			Manifestation of overdose symptoms	
mg/dl	mEq/l	mmol/l		
<1.2	<1	<0.5	• Tetany • Seizures	• Arrhythmias
1.2-1.8	1.0-1.5	0.5-0.75	• Neuromuscular irritability • Hypocalcaemia	• Hypokalaemia
1.8-2.5	1.5-2.1	0.75-1.05	• Normal magnesium level	
2.5-5.0	2.1-4.2	1.05-2.1	• Typically asymptomatic	
5.0-7.0	4.2-5.8	2.1-2.9	• Lethargy • Drowsiness • Diminished deep tendon reflex	• Nausea and vomiting • Flushing
7.0-12	5.8-10	2.9-5	• Somnolence • Loss of deep tendon reflexes	• Hypotension • ECG changes
>12	>10	>5	• Complete heart arrest • Apnoea	• Paralysis • Coma

Treatment

In symptomatic hypermagnesaemia, administration of calcium, usually at a dose of 100 to 200 mg intravenously over 5 to 10 min, antagonizes the toxic effects of magnesium.

In patients with severe renal dysfunction, peritoneal dialysis or haemodialysis will rapidly and effectively lower serum magnesium levels.