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 this medicine?

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

This medicine contains the active substance, magnesium sulfate heptahydrate, which plays a number of important roles in the body, and is involved in the regulation of the nervous and blood systems. This medicine is a solution for injection or infusion and is used for magnesium deficiency and 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 use Magnesium Sulfate 50% w/v Solution for Injection or Infusion

Do not use this medicine if you:

- Are allergic to magnesium or its salts
- Suffer from heart disease
- Suffer from impaired kidney function
- Have/had liver failure
- Have/had kidney failure
- Suffer from a disease of the brain associated with cirrhosis of the liver
- Are pregnant
- Are breast feeding

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

Warnings and Precautions

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

- Are breast feeding
- Have heart disease
- Have liver or kidney disease
- Are pregnant
- Have/had kidney failure
- Have/had liver failure
- Suffer from a disease of the brain associated with cirrhosis of the liver

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important if you are taking:

- Digitalis glycosides
- Rilفيدine
- Muscle relaxants or central nervous system depressants such as sedatives

Check with your doctor if you are concerned about any of the above.

3. How to use Magnesium Sulfate 50% w/v Solution for Injection or Infusion

The doctor will decide what dose of this medicine you should be given. Check the label carefully. If you are not sure about anything, ask your doctor, nurse or pharmacist.

The recommended dose for the treatment of magnesium deficiency is:

Up to 160mmol of magnesium given by slow intravenous infusion (using concentrations not greater than 20% w/v) over a maximum of 5 days. If further treatment is required, for example during prolonged feeding by drip, the usual daily dose is about 12mmol of magnesium.

The recommended dose for the prevention and control of fits associated with severe pre-eclampsia and eclampsia is:

An initial intravenous dose of 4g, given slowly over a period of 20 minutes or so, is followed by an infusion of 1g/hour. If necessary, regular injections of 5g can be made into the buttocks every 4 hours, for at least 24 hours after the last fit. If fits recur a further 2 - 4g is given intravenously over 5 minutes.

You may be given (prescribed) a different dose by your doctor if you have problems with your kidneys.

If swallowed this medicine may cause stomach irritation and watery diarrhoea. If any of this medicine is swallowed tell your doctor immediately.

4. Possible Side Effects

The most common side effects are:

- Thirst
- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Flushed face

Serious side effects which are very rare are:

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

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

Additional information for Healthcare Professionals

(As stated on the Summary of Product Characteristics)

Therapeutic Indications

(a) Treatment of magnesium deficiency in hypomagnesaemia.
(b) Prevention and control of generalised seizures in patients with severe pre-eclampsia or eclampsia.

Posology and Method of Administration

Dosages should be adjusted according to the patient's needs and responses. Plasma levels should also be monitored during treatment.

(a) Treatment of magnesium deficiency in hypomagnesaemia:

Up to 160mmol Mg2+ by slow intravenous infusion (in glucose 5%) for up to 5 days, may be required to replace the deficit (allowing for urinary losses). Concentrations of no higher than 20%w/v should be given intravenously.

Treatment may require repetition, for example during prolonged intravenous nutrition magnesium deficiency can occur, then parenteral doses of magnesium are of the order of 10 to 20mmol Mg2+ daily (often about 12mmol Mg2+ daily).

Dosage for the elderly is similar to that for younger adults. Magnesium Sulfate 50% w/v Solution for Injection or Infusion should not be given to children. Appropriate reductions in dosage should be made for patients with renal impairment.
4. Possible side effects

Like all medicines, this medicine 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)
- Muscle weakness

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
- Drowsiness

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

**Reporting of Side Effects**

If you get any side effects, talk to your doctor, nurse or pharmacist. 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.
- This medicine has an expiry date printed on the ampoule, vial and carton. Do not use this medicine after the expiry date. The expiry date refers to the last day of the month.
- Before use the doctor or nurse will check the medicine has not passed this date and that the medicine does not show any sign of deterioration.
- Only use this medicine if it is particle free.
- Keep the container in the original outer carton.
- Store between 2 - 25°C.
- After the expiry date, any unused medicine should be returned to a pharmacy.
- Do not throw away any medicines via waste water. 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 Hexahydrate at a strength of 500mg per litre (approximately 2mmol magnesium per mL).
  - 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 contains 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 and South Devon NHS Foundation Trust, Torbay Pharmaceuticals, Wilkins Drive, Paignton, Devon, TQ4 7FG, UK
  - +44 (1803) 684707
  - tcdt.medinfo@torbaypharmaceuticals.nhs.net
  - This leaflet was last revised in: 09/2018
  - PIL/4/9

(b) Prevention and control of seizures associated with severe pre-eclampsia and eclampsia:

An initial intravenous (IV) loading dose of typically 4g (approximately 16mmol Mg²⁺) given slowly over a period of 20 minutes or so, at a strength no higher than 20% w/v, is followed by ideally an IV infusion, or if this is not possible by regular intramuscular (IM) injections as follows:

- Coma

Intravenous Maintenance Regimen: The loading dose is followed by an intravenous infusion of 1g (approximately 4mmol Mg²⁺) per hour, continued for 24 hours after last fit.

Intramuscular Maintenance Regimen: The loading dose is followed by 5g (approximately 20mmol Mg²⁺), usually in 50% solution, as deep IM injection into the upper outer quadrant of each buttock. The intramuscular injection is painful.

Maintenance therapy is a further 5g every 4 hours continued for 24 hours after the last fit (provided the respiratory rate is > 16 per minute, urine output >25mL per hour and knee jerks are present).

Recurrent convulsions: In both the IV and IM regimens, if convulsions recur, a further 2 - 4g (approximately 8 - 16mmol Mg²⁺), depending on the woman's weight, 2g if less than 70kg, is given IV over 5 minutes.

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 (approximately 80mmol Mg²⁺) over 48 hours.

Incompatibilities

Not applicable.