Magnesium Sulfate

**Ingredients:** Magnesium Sulfate  
**Indications:** Hypomagnesemia; Eclampsia; Pre-eclampsia  
**Off-label Indications:** Clinically relevant: Premature Labor; Torsades de Pointes; Not clinically relevant: Asthma, Acute; Myocardial Infarction; Tocolysis.  
**FDA Approved 1986-09-01.**  
**DRUG CLASS:** Electrolyte replacements; Vitamins/minerals.  

**Brand Names:** Sulfamag (US) *(International brand names outside U.S. in italics).*

**DESCRIPTION:**

- **50%**  
  4.06 mEq/ml.  
  4.06 mOsm/ml.  
- **10%**  
  0.8 mEq/ml.  
  0.8 mOsm/ml.

**Magnesium** sulfate injection is a sterile, non-pyrogenic solution of **magnesium** sulfate in water for injection.  
Each ml of the 50% solution contains 500 mg of **magnesium** sulfate heptahydrate.  
Each ml of the 10% solution contains 100 mg of **magnesium** sulfate heptahydrate.  
The pH of either solution may be adjusted with sodium hydroxide and/or sulphuric acid to between 5.5-7.0 when diluted to a 5% concentration (w/v).  
The solution contains no bacteriostatic agent or other preservatives.

**Magnesium** sulfate heptahydrate is chemically designated MgSO$_4$·7H$_2$O and occurs as a white, bitter, crystalline powder which is freely soluble in water.  

**CLINICAL PHARMACOLOGY:**

**Magnesium** is the second most plentiful cation of the intracellular fluids. It is essential for the activity of many enzyme systems and plays an important role with regard to neurochemical transmission and muscular excitability. Deficits are accompanied by a variety of structural and functional disturbances.

Some of the effects of **magnesium** on the nervous system are similar to those of calcium. An increased concentration of **magnesium** in the extracellular fluid causes depression of the central nervous system (CNS). **Magnesium** has a direct depressant effect on skeletal muscle.

Abnormally low concentrations of **magnesium** in the extracellular fluid result in increased acetylcholine release and increased muscle excitability that can produce tetany.

**Magnesium** slows the rate of S-A nodal impulse formation. Higher concentrations of **magnesium** (greater than 15 mEq/L) produce cardiac arrest in diastole. Excess **magnesium** causes vasodilatation by both a direct action on blood vessels and ganglionic blockade. **Magnesium** is excreted principally by the kidney by glomerular filtration.

**INDICATIONS AND USAGE:**

**Magnesium** sulfate may be of therapeutic value in the following conditions:

As a CNS depressant, primarily in preeclampsia and eclampsia of pregnancy.  
As an electrolyte replenisher for hypomagnesemia and **magnesium** deficiency to maintain normal neuromuscular irritability.
CONTRAINDICATIONS:

Magnesium sulfate should not be administered parenterally in patients with heart block or myocardial damage.

WARNINGS:

The principal hazard in parenteral magnesium therapy is the production of abnormally high levels of magnesium in the plasma. The most immediate danger to life is respiratory depression. A preparation of calcium, such as the gluconate or gluceptate, should be at hand for intravenous administration as an antidote.

Magnesium sulfate can cause fetal harm when administered to a pregnant woman. When magnesium sulfate is administered to a toxic mother, the newborn is usually not compromised. When Magnesium Sulfate, USP is administered intravenously by a continuous infusion for longer than 24 hours before delivery, the possibility of the baby’s showing signs of neuromuscular or respiratory depression of the newborn should be considered, since fetal toxicity can occur. A baby with hypermagnesemia may require resuscitation and assisted ventilation. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

PRECAUTIONS:

General

Administer with caution if flushing and sweating occurs.

When barbiturates, narcotics or other hypnotics (or systemic anesthetics) are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of additive CNS depressant effects of magnesium. A preparation of calcium salt should be readily available for intravenous injection to counteract potential serious signs of magnesium intoxication.

Since Magnesium is excreted almost entirely by the kidneys, it should be given very cautiously in the presence of serious impairment of renal function.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Studies with magnesium sulfate in water for injection have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Laboratory Tests

Magnesium sulfate should not be given unless hypomagnesemia has been confirmed and the serum concentration of magnesium is monitored. The normal serum level is 1.5 to 2.4 mEq/L.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when magnesium sulfate is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

INTERACTIONS:

When barbiturates, narcotics, hypnotics (or systemic anesthetics), or other central nervous system depressants are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of the additive central nervous system depressant effects of magnesium.
Central nervous system depression and peripheral transmission defects produced by magnesium may be antagonized by calcium.

**ADVERSE REACTIONS:**

Principal adverse reactions are related to the high plasma levels of magnesium and include flushing, sweating, hypotension, circulatory collapse, and cardiac and central nervous system depression. Respiratory depression is the most life-threatening effect.

**OVERDOSAGE:**

Hypermagnesemia is manifested by muscle weakness, hypotension, ECG changes, sedation, and confusion. As plasma concentrations of magnesium begin to exceed 4 mEq/L, the deep-tendon reflexes are decreased and may be absent at levels approaching 10 mEq/L. At 12 to 15 mEq/L respiratory paralysis is a potential hazard; the respiratory effects can be antagonized to some extent by the intravenous administration of calcium salts. In cases of severe renal impairment, symptomatic hypermagnesemia may be an indication for dialysis. Although man usually tolerates high concentrations of magnesium in plasma, there are occasional instances when cardiac consequences may be seen in the form of complete heart block at concentrations well below 10 mEq/L.

Before the parenteral administration of each dose, the respiratory rate should be at least 16 per minute and urinary function should be adequate. In the event of overdosage, assisted ventilation must be provided until calcium can be given intravenously. Peritoneal dialysis or hemodialysis may be required in cases of extreme hypermagnesemia. When magnesium sulfate is administered parenterally in doses that are sufficient to induce hypermagnesemia, the drug has a depressant effect on the central nervous system and, via the peripheral neuromuscular junction, on muscle.

**DOSAGE AND ADMINISTRATION:**

**Intramuscular:** Adults and older children for severe hypomagnesemia 1-5 g (2-10 ml of 50% solution) daily in divided doses; administration is repeated daily until serum levels have returned to normal. If deficiency is not severe 1 g (2 ml of 50% solution) can be given once or twice daily. Serum magnesium levels should serve as a guide to continued dosage.

**Intravenous:** 1 to 4 g magnesium sulfate 50% may be given intravenously in 10% to 20% solution, but only with great caution; the rate should not exceed 1.5 ml of 10% solution or equivalent per minute until relaxation is obtained.

**Intravenous Infusion:** 4 g in 150 ml of 5% Dextrose Injection, USP at a rate not exceeding 3 ml per minute.

**Usual Dose Range:** 1 to 40 g daily.

**Electrolyte Replenisher:** Intramuscular 1 to 2 g in 50% solution four times a day until serum magnesium is within normal limits.

**Usual Pediatric Dose:** Intramuscular 20 to 40 mg/kg of body weight in a 20% solution repeated as necessary.

**For Eclampsia:** Initially 1 to 2 g in 25% or 50% solution is given intramuscularly. Subsequently, 1 g is given every 30 minutes until relief is obtained. The blood pressure should be monitored after each injection.

Parenteral drug products should be visually inspected for particulate matter and discoloration prior to administration, whenever solution and container permit.