For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only.

℞ Magnesium Sulphate Injection IP

Magsocan 50%
Injection

Composition :
Each ml contains :
Magnesium Sulphate Heptahydrate I.P. 500 mg
Water for Injection I.P. q.s.
Approx-2.0 millimoles Magnesium Ions (mg^{++}) in per ml

For I.M. / I.V. Use Only

DESCRIPTION:
Magnesium Sulfate Injection, IP 50% is a sterile, nonpyrogenic, concentrated solution of magnesium sulfate in Water for Injection. It is administered by the intravenous (IV) or intramuscular (IM) routes as an electrolyte replenisher or anticonvulsant. Must be diluted before IV use. Each mL contains: Magnesium sulfate 500 mg; Water for Injection q.s. Is intended only for use as a single dose injection. When smaller doses are required the unused portion should be discarded with the entire unit. Magnesium sulfate is chemically designated $MgSO_4$, occurs as colorless crystals or white powder freely soluble in water.

CLINICAL PHARMACOLOGY:
Magnesium is an important cofactor for enzymatic reactions and plays an important role in neuro- chemical transmission and muscular excitability. As a nutritional adjunct in hyperalimentation, the precise mechanism of action for magnesium is uncertain. Early symptoms of hypomagnesemia (less than 1.5 mEq/L) may develop as early as three to four days or within weeks. Predominant deficiency effects are neurological, e.g., muscle irritability, clonic twitching and tremors. Hypocalcemia and hypokalemia often follow low serum levels of magnesium. While there are large stores of magnesium present intracellularly and in the bones of adults, these stores often are not mobilized sufficiently to maintain plasma levels. Parenteral magnesium therapy repairs the plasma deficit and causes deficiency symptoms and signs to cease. Magnesium prevents or controls convulsions by blocking neuromuscular transmission and decreasing the amount of acetylcholine liberated at the end-plate by the motor nerve impulse. Magnesium is said to have a depressant effect on the central nervous system (CNS), but it does not adversely affect the woman, fetus or neonate when used as directed in eclampsia or pre-eclampsia. Normal plasma magnesium levels range from 1.5 to 2.5 mEq/L. As plasma magnesium rises above 4 mEq/L, the deep tendon reflexes are first decreased and then disappear as the plasma level approaches 10 mEq/L. At this level respiratory paralysis may occur. Heart block also may occur at this or lower plasma levels of magnesium. Serum magnesium concentrations in excess of 12 mEq/L may be fatal. Magnesium acts peripherally to produce vasodilation. With low doses only flushing and sweating occur, but larger doses cause lowering of blood pressure. The central and peripheral effects of magnesium poisoning are antagonized to some extent by IV administration of calcium.

Pharmacokinetics
With IV administration the onset of anticonvulsant action is immediate and lasts about 30 minutes. Following IM administration, the onset of action occurs in about one hour and persists for three to four hours. Effective anticonvulsant serum levels range from 2.5 to 7.5 mEq/L. Magnesium is excreted solely by the kidneys at a rate proportional to the plasma concentration and glomerular filtration.

INDICATIONS AND USAGE:
Magnesium Sulfate Injection, USP is suitable for replacement therapy in magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those observed in hypocalcemia. In such cases, the serum magnesium level is usually below the lower limit of normal (1.5 to 2.5 mEq/L) and the serum calcium level is normal (4.3 to 5.3 mEq/L) or elevated. In total parenteral nutrition (TPN), magnesium sulfate may be added to the nutrient admixture to correct or prevent hypomagnesemia which can arise during the course of therapy. Magnesium sulfate injection is also indicated for the prevention and control of seizures in pre- eclampsia and eclampsia, respectively.

CONTRAINDICATIONS:
Parenteral administration of the drug is contraindicated in patients with heart block or myocardial damage.

WARNINGS:
FETAL HARM: Continuous administration of magnesium sulfate beyond 5 to 7 days to pregnant women can lead to hypocalcemia and bone abnormalities in the developing fetus. These bone abnormalities include skeletal demineralization and osteopenia. In addition, cases of neonatal fracture have been reported. The shortest duration of treatment that can lead to fetal harm is not known. Magnesium sulfate should be used during pregnancy only if clearly needed. If magnesium sulfate is given for treatment of preterm labor, the woman should be informed that the efficacy and safety of such use have not been established and that use of magnesium sulfate beyond 5 to 7 days may cause fetal abnormalities.

Parenteral use in the presence of renal insufficiency may lead to magnesium intoxication. IV use in eclampsia should be reserved for immediate control of life-threatening convulsions.

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.
Because magnesium is removed from the body solely by the kidneys, the drug should be used with caution in patients with renal impairment. Urine output should be maintained at a level of 100 mL or more during the four hours preceding each dose. Monitoring serum magnesium levels and the patient's clinical status is essential to avoid the consequences of overdosage in toxemia. Clinical indications of a safe dosage regimen include the presence of the patellar reflex (knee jerk) and absence of respiratory depression (approximately 16 breaths or more/min). When repeated doses of the drug are given parenterally, knee jerk reflexes should be tested before each dose and if they are absent, no additional magnesium should be given until they return. Serum magnesium levels usually sufficient to control convulsions range from 3 to 6 mg/100 mL (2.5 to 5 mEq/L). The strength of the deep tendon reflexes begins to diminish when magnesium levels exceed 4 mEq/L. Reflexes may be absent at 10 mEq magnesium/L, where respiratory paralysis is a potential hazard. An injectable calcium salt should be immediately available to counteract the potential hazards of magnesium intoxication in eclampsia. Magnesium sulfate injection (50%) must be diluted to a concentration of 20% or less prior to IV infusion. Rate of administration should be slow and cautious, to avoid producing hypermagnesemia. The 50% solution

Laboratory Tests
Magnesium sulfate injection 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 2.5 mEq/L.
Drug Interactions
CNS Depressants—When barbiturates, narcotics or other hypnotics (or systemic anesthetics), or other CNS depressants are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of additive CNS depressant effects of magnesium. CNS depression and peripheral transmission defects produced by magnesium may be antagonized by calcium.
Neuromuscular Blocking Agents—Excessive neuromuscular block has occurred in patients receiving parenteral magnesium sulfate and a neuromuscular blocking agent; these drugs should be administered concomitantly with caution.
Cardiac Glycosides—Magnesium sulfate should be administered with extreme caution in digitalized patients, because serious changes in cardiac conduc- tion which can result in heart block may occur if administration of calcium is required to treat magnesium toxicity.

Pregnancy Teratogenic Effects:
Pregnancy Category D (See WARNINGS and PRECAUTIONS) See WARNINGS and PRECAUTIONS.
Magnesium sulfate can cause fetal abnormalities when administered beyond 5 to 7 days to pregnant women. There are retrospective epidemiological studies and case reports documenting fetal abnormalities such as hypocalcemia, skeletal demineralization, osteopenia and other skeletal abnormalities with continuous maternal administration of magnesium sulfate for more than 5 to 7 days.1-10 Magnesium sulfate injection should be used during pregnancy only if clearly needed. If this drug is used during pregnancy, the woman should be apprised of the potential hazard to the fetus.
Nonteratogenic Effects:
When administered by continuous IV infusion (especially for more than 24 hours preceding delivery) to control convulsions in a toxemic woman, the newborn may show signs of magnesium toxicity, including neuromuscular or respiratory depression.
Labor and Delivery
Continuous administration of magnesium sulfate is an unapproved treatment for preterm labor. The safety and efficacy of such use have not been established. The administration of magnesium sulfate outside of its approved indication in pregnant women should be by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.
Nursing Mothers
Since magnesium is distributed into milk during parenteral magnesium sulfate administration, the drug should be used with caution in nursing women.
Geriatrics
Geriatric patients often require reduced dosage because of impaired renal function. In patients with severe impairment, dosage should not exceed 20 g in 48 hours. Serum magnesium should be monitored in such patients.
ADVERSE REACTIONS:
The adverse effects of parenterally administered magnesium usually are the result of magnesium intoxication. These include flushing, sweating, hypotension, depressed reflexes, flaccid paralysis, hypothermia, circulatory collapse, cardiac and CNS depression proceeding to respiratory paralysis. Hypocalcemia with signs of tetany secondary to magnesium sulfate therapy for eclampsia has been reported.

OVERDOSAGE:
Magnesium intoxication is manifested by a sharp drop in blood pressure and respiratory paralysis. Disappearance of the patellar reflex is a useful clinical sign to detect the onset of magnesium intoxication. In the event of overdosage, artificial ventilation must be provided until a calcium salt can be injected IV to antagonize the effects of magnesium.
For Treatment of Overdose
Artificial respiration is often required. Intravenous calcium, 10 to 20 mL of a 5% solution (diluted if desirable with isotonic sodium chloride for injection) is used to counteract effects of hypermagnesemia. Subcutaneous physostigmine, 0.5 to 1 mg may be helpful. Hypermagnesemia in the newborn may require resuscitation and assisted ventilation via endotracheal intubation or intermittent positive pressure ventilation as well as IV calcium.

DOSAGE AND ADMINISTRATION:
Dosage of magnesium sulfate must be carefully adjusted according to individual requirements and response, and administration of the drug should be discontinued as soon as the desired effect is obtained. Both IV and IM administration are appropriate. IM administration of the undiluted 50% solution results in therapeutic plasma levels in 60 minutes, whereas IV doses will provide a therapeutic level almost immediately. The rate of IV injection should generally not exceed 150 mg/minute (1.5 mL of a 10% concentration or its equivalent), except in severe eclampsia with seizures. Continuous maternal administration of magnesium sulfate in pregnancy beyond 5 to 7 days can cause fetal abnormalities. Solutions for IV infusion must be diluted to a concentration of 20% or less prior to administration. The diluents commonly used are 5% Dextrose Injection, USP and 0.9% Sodium Chloride Injection, USP. Deep IM injection of the undiluted (50%) solution is appropriate for adults, but the solution should be diluted to a 20% or less concentration prior to such injection in children.
In Magnesium Deficiency
In the treatment of mild magnesium deficiency, the usual adult dose is 1 g, equivalent to 8.12 mEq of magnesium (2 mL of the 50% solution) injected IM every six hours for four doses (equivalent to a total of 32.5 mEq of magnesium per 24 hours). For severe hypomagnesemia, as much as 250 mg (approximately 2 mEq) per kg of body weight (0.5 mL of the 50% solution) may be given IM within a period of four hours if necessary. Alternatively, 5 g (approximately 40 mEq) can be added to one liter of 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP for slow IV infusion over a three-hour period. In the treatment of deficiency states, caution must be observed to prevent exceeding the renal excretory capacity.
In Hyperalimentation

Storage : Store below 30 C. Protect from light. Do not freeze
Improper storage may deteriorate the product.

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