

MAGNESIUM SULFATE - magnesium sulfate heptahydrate injection, solution **General Injectables & Vaccines, Inc**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

50 % Magnesium Sulfate 0.5 gm/mL Injection, USP 2 mL Single Dose Vial

Description

2.03 mM/mL of Magnesium Sulfate Heptahydrate

Osmolarity 4.06 mOsmol/mL

MUST BE DILUTED PRIOR TO IV ADMINISTRATION

Magnesium Sulfate Injection, USP (50%) for IV and IM use is a sterile concentrated solution of Magnesium Sulfate USP. Each mL contains: Magnesium Sulfate (Heptahydrate) 500 mg, which provides 4.06 mEq each of Magnesium (Mg⁺⁺) and Sulfate (SO₄⁼), Water for Injection q.s. The pH (5.5 - 7.0) is adjusted with Sulfuric Acid and/or Sodium Hydroxide. The solution contains no bacteriostatic agent or other preservatives. The molecular formula is MgSO₄ • 7H₂O and the molecular weight is 246.47.

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.

Indications and Usage

Magnesium Sulfate is indicated in the following conditions:

Convulsions (treatment) - Intravenous magnesium sulfate is indicated for immediate control of life threatening convulsions in the treatment of severe toxemias (pre-eclampsia and eclampsia) of pregnancy and in the treatment of acute nephritis in children.

Hypomagnesemia (prophylaxis and treatment) - Magnesium Sulfate is indicated for replacement therapy in magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those of hypocalcemia.

Magnesium Sulfate is also used to prevent or treat magnesium deficiency in patients receiving total parenteral nutrition.

Tetany, uterine (treatment) - Magnesium Sulfate is indicated in uterine tetany as a myometrial relaxant.

Contraindications

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

Warnings

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

The principle hazard in parenteral magnesium therapy is the production of abnormally high levels of

magnesium in the plasma. Such high levels may cause flushing, sweating, hypotension, circulatory collapse and depression of cardiac and central nervous system function. The most immediate danger to life is respiratory depression.

During the period of parenteral therapy with magnesium salts, the patient should be watched carefully. A preparation of calcium, such as the gluconate or gluceptate should be at hand for intravenous administration as an antidote.

In the presence of severe renal insufficiency, no more than 20 grams of magnesium should be given within a forty-eight hour period. In eclampsia, however, renal function is not seriously impaired and magnesium may be more rapidly excreted.

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Precautions

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 the additive central depressive effects of magnesium.

Pregnancy - Teratogenic effects: Pregnancy category C. Animal reproduction studies have not been conducted with Magnesium Sulfate Injection, USP 50%. It is also not known whether Magnesium Sulfate Injection, USP 50% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Magnesium Sulfate Injection, USP 50% should be given to a pregnant woman only if clearly needed.

Adverse Reactions

Flushing, sweating, sharply lowered blood pressure, hypothermia, stupor and ultimately, respiratory depression.

Dosage and Administration

Intramuscular: Adults and older children: For severe hypomagnesemia, 1 to 5 g (2 to 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 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 250 mL of 5% Dextrose Injection 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 per 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 inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

How Supplied

Product No.	Vial Sizes	
NDC 0517-2602-25	2 mL Single Dose vial	Boxes of 25
NDC 0517-2610-25	10 mL Single Dose vial	Boxes of 25
NDC 0517-2650-25	50 mL Single Dose vial	Boxes of 2

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Discard unused portion.

IN0291

Rev. 1/09

MG #7879

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

MAGNESIUM
SULFATE
INJECTION, USP 50%
Rx Only

Sample Outer Label

NDC # 52584-602-25
LOT # XXXX
Exp: mm-yy
Serial # XXXXXX

PACKAGED BY GIV
BASTIAN, VA 24314

50% MAGNESIUM SULFATE
0.5 gm/ml INJECTION, USP
2 ml Single Dose Vial

SEE MANUFACTURER'S INSERT
FOR COMPLETE PRODUCT AND
PRESCRIBING INFORMATION

Keep out of
children's reach.

Store at controlled room
temperature 68F to 77F.
Excursions permitted to 59-86F

FOR IM USE
FOR IV USE AFTER DILUTION

MANUFACTURER INFORMATION

American Regent, Inc.

ORIG MFG LOT: XX-XXX-XX



0517-2602-25



Item # 2582820

RX ONLY

MAGNESIUM SULFATE

magnesium sulfate heptahydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52584-602(NDC:0517-2602)
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Magnesium Sulfate Heptahydrate (UNII: SK47B8698T) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Sulfate Heptahydrate	0.5 g in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52584-602-25	1 in 1 BAG		
1		2 mL in 1 VIAL, SINGLE-DOSE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2010	

Labeler - General Injectables & Vaccines, Inc (108250663)

Establishment			
Name	Address	ID/FEI	Business Operations
General Injectables & Vaccines, Inc		108250663	relabel

Revised: 8/2010

General Injectables & Vaccines, Inc