MAGNESIUM CHLORIDE- magnesium chloride injection
Mylan Institutional LLC

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.

DESCRIPTION

Magnesium Chloride Injection is a sterile solution of Magnesium Chloride Hexahydrate in Water for Injection q.s. Each mL contains Magnesium Chloride Hexahydrate 200 mg, Sodium Chloride 9 mg, Benzyl Alcohol 1% as a preservative, Water for Injection, q.s. pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide. Total osmolarity equivalent to 2.951 mOsm/mL.

Contains 1.97 mEq of Mg^{++} and Cl^{-} per mL.

The structural formula is $MgCl_2 \cdot 6H_2O$

ACTIONS

Magnesium is the second most plentiful cation within cellular fluids. It is an important activator of many enzyme systems and deficits are accompanied by a variety of functional disturbances.

INDICATIONS

As an electrolyte replenisher in magnesium deficiencies.

CONTRAINDICATIONS

Magnesium Chloride Injection should not be administered if there is renal impairment, marked myocardial disease or to comatose patients.

WARNING

Do not use if a precipitate is present.

PRECAUTIONS

The usual precautions for parenteral administration should be observed. Administer with caution if flushing and sweating occurs. A preparation of a calcium salt should be readily available for intravenous injection to counteract potential serious signs of magnesium intoxication. As long as deep tendon reflexes are active it is probable that the patient will not develop respiratory paralysis. Respiration and blood pressure should be carefully observed during and after administration of Magnesium Chloride Injection.

Pregnancy

Animal reproduction studies have not been conducted with magnesium chloride. It is also not known whether magnesium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Magnesium Chloride 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

For intravenous infusion: 4 grams in 250 mL of 5% Dextrose Injection, at a rate not exceeding 3 mL per minute. Serum magnesium levels should serve as a guide to continued dosage.

USUAL DOSAGE RANGE

1 to 40 grams daily.

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

HOW SUPPLIED

Magnesium Chloride Injection 200 mg/mL (20% w/v).

NDC 67457-134-50
50 mL Multiple-Dose Vial. Individually boxed.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured for:
Mylan Institutional LLC
Morgantown, WV 26505

Manufactured by:
Mylan Institutional
Galway, Ireland

1084L101
Revised: 10/2021
MI:MAGNIJ:R4

PRINCIPAL DISPLAY PANEL - 200 mg/mL

NDC 67457-134-50 50 mL

Magnesium

Chloride Injection

200 mg/mL (20% w/v)

2.951 mOsm/mL

For Intravenous Use After Dilution

Rx only Multiple-Dose Vial

Each mL contains: Magnesium Chloride Hexahydrate 200 mg, Sodium Chloride 9 mg, Benzyl Alcohol 1% as a preservative, Water for Injection q.s. pH adjusted with Hydrochloric Acid and/or Sodium Hydroxide.

Total osmolarity equivalent to 2.951 mOsm/mL.

Contains 1.97 mEq of Mg^{++} and Cl^{-} per mL.

WARNING: DO NOT USE IF A PRECIPITATE IS PRESENT.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Usual Dosage: See accompanying prescribing information.

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MI:134:1C:R5

Mylan.com

MAGNESIUM CHLORIDE

magnesium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:67457-134
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM CHLORIDE (UNII: 02F3473H9O) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CHLORIDE	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67457-134-50	1 in 1 CARTON	03/14/2013	
1		50 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		03/14/2013	

Labeler - Mylan Institutional LLC (790384502)

Revised: 10/2021 Mylan Institutional LLC