

# LAVOISIER MAGNESIUM CHLORIDE 10 % (1 g/10 ml), IV injectable solution

## QUALITATIVE AND QUANTITATIVE COMPOSITION

SPECIALTY DOSE	1 g/10 ml
MAGNESIUM CHLORIDE HEXAHYDRATE	1.0 g
Corresponding quantity in magnesium element	0.12 g
Water for injectable solutions	s.q 10 ml

in each single dose ampoule

Magnesium element: 492 mmol/l, i.e. 12 g/l

Solution total osmolarity: 1 476 mOsmol/l

## PHARMACEUTICAL FORM

IV Injectable solution.

## THERAPEUTIC INDICATIONS

- Curative treatment of torsades de pointe (TdP).
- Treatment of acute hypokalemia associated with hypomagnesemia.
- Magnesium supplement during electrolyte rebalance.
- Magnesium supplement in parenteral nutrition.
- Preventive and curative treatment of eclampsia crisis.

## POSODOLOGY AND ADMINISTRATION

### Posology:

#### Curative treatment of torsades de pointe:

Intravenous bolus in 8 mmol of magnesium cation, i.e. 1.6 g of magnesium chloride in slow intravenous injection, followed by continuous infusion from 0.012 to 0.08 mmol of magnesium cation per minute, i.e. 2.5 to 16.5 mg/minute of magnesium chloride.

#### Treatment of acute hypokalaemia associated with hypomagnesemia:

Intravenous infusion from 24 to 32 mmol of magnesium cation daily, i.e. 5 to 6.5 g of magnesium chloride by 24 hours with potassium supplementation. Potassium supplementation must be dispensed from a container different from that of magnesium. Discontinuance of treatment once magnesium levels return to normal.

#### Magnesium supplementation in electrolyte rebalance and parenteral nutrition:

Intravenous infusion from 6 to 8 mmol of magnesium cation over 24 hours, i.e. 1.2 to 1.6 g of magnesium chloride.

In children, the usual posology is 0.1 to 0.3 mmol/kg/24h of magnesium cation, i.e., 20 to 60 mg magnesium chloride/kg over 24 hours.

#### Preventive and curative treatment of eclampsia crisis:

Slow intravenous injection.

To prevent eclampsia or when it occurs, administer an intravenous infusion in 16 mmol of magnesium cation, i.e. 3.5 g of magnesium chloride for 20 to 30 minutes.

If eclampsia persists, repeat IV intravenous infusion in 16 mmol of magnesium, cation, i.e. 3.5 g of magnesium chloride, without exceeding the maximal accumulated dose in 32 mmol of magnesium cation, i.e., 6.5 g of magnesium chloride for the first hour of treatment.

Afterward continuous intravenous infusion from 8 to 12 mmol of magnesium cation (i.e. 1.5 to 2.0 g of magnesium chloride) per hour for the 24 hours following the last attack.

Generally in adults, to avoid potentially life-threatening hypermagnesemia, intravenous infusion should never exceed 120 mg/minute, i.e. 0.6 mmol/minute.

### Administration:

Magnesium chloride solution must be administered:

- In slow intravenous injection, the patient lying down, direct intravenous injection (in bolus) being only used for the treatment of torsades de pointe (TdP) and performed in specialized setting.
- Diluted in glucose or saline solution.

## CONTRA-INDICATIONS

This drug should never be prescribed for patients with severe renal insufficiency (creatinine clearance under 30 ml/min/1.73 m<sup>2</sup>).

## SPECIAL WARNINGS AND PRECAUTIONS FOR USE

HYPERTONIC SOLUTION TO BE INJECTED SLOWLY.

- The first intravenous injections should be performed at hospital.
- Infusion should be performed slowly, at a rate not exceeding 0.6 mmol of magnesium cation per minute, i.e. 120 mg magnesium chloride per minute, i.e. 120 mg magnesium chloride per minute.
- Blood pressure monitoring during intravenous injection and continuous infusion.
- Magnesemia monitoring: suspension of treatment when levels return to normal
- Reduce the posology in patients with renal insufficiency and have their renal function, blood pressure and magnesium levels closely monitored.
- Do not use concomitantly with calcium salts (antagonistic effect).

## INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

### Contraindicated interactions:

- **Quinidinic:** Increase of plasma concentrations of quinidine with risk of overdosage (decreased renal).

### Associations requiring extreme caution:

- **Curares:** because of the potential for prolonged neuromuscular block.

## PREGNANCY AND LACTATION

In clinical trials, the use of magnesium in pregnancy, in a small number of women has not shown any particular malformative or foetotoxic effect until now. However, confirmatory experimental evidence is needed to evaluate the implications of an exposure in pregnancy.

Consequently, magnesium should be used in pregnancy only if absolutely necessary. As magnesium passes into the breast milk, breast-feeding should be discontinued during treatment.

## ADVERSE REACTION

- Pain at the point of injection, vasodilatation with feeling of heat.
- Hypermagnesemia potentially life-threatening in patients with severe renal insufficiency or when injection rate is too fast.

## OVERDOSAGE

The first signs of hypermagnesemia include inhibition of knee jerks, feeling of heat, drowsiness, spoken speech disorders, muscular paralysis with respiratory disorders and at the most, respiratory and cardiac arrest.

### Treatment

- Rehydration, forced diuresis, assisted ventilation
- IV Injection of 1 g of calcium gluconate
- Hemodialysis or peritoneal dialysis in patients with renal insufficiency.

## CLINICAL PHARMACOLOGY

### Pharmacodynamics

#### MAGNESIUM SALTS SOLUTION

(B 05 CB) (B: Hematopoietic stem cells blood and lymphoid organs)

#### Physiologically:

Magnesium is a cation primarily intracellular. It decreases neuronal excitability and neuromuscular transmission and is involved in several enzymatic reactions. Constitutional element, half of magnesium builds bone mass.

#### Clinically:

Serum magnesemia:

- ranging from 12 to 17 mg/l (1 to 1.4 mEq/l or 0.5 to 0.7 mmol/l) indicates moderate magnesium deficiency,
- under 12 mg/l (1 mEq/l or 0.5 mmol/l) indicates severe magnesium deficiency

Magnesium deficiency may be:

- Primary by congenital abnormality of metabolism (chronic congenital hypomagnesemia).
- Secondary by:
  - . inadequate nutritional supplements (severe denutrition, alcoholism, parenteral nutrition exclusively),
  - . digestive malabsorption (chronic diarrhoea, digestive fistulas, hypoparathyroidies),
  - . excessive increase of renal losses (tubulopathies, polyurias, diuretics abuse, chronic pyelonephritis, primary hyperaldosteronism, treatment with cisplatin).

### Pharmacokinetics

Urinary excretion mainly.

## PHARMACEUTICAL DATA

### Incompatibilities

Magnesium chloride in solution may precipitate when mixed with magnesium-content solutions:

- alcohol with high concentration
- alkaline carbonates, bicarbonates and hydroxides
- calcium salts,
- tartrates, salicylates,
- procaine
- clindamycin phosphate
- hydrocortisone sodium succinate

### Shelf life

5 years

### Nature and contents of container

10 ml ampoule bottle (type I glass); 10 or 100 units pack

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging:

#### Ampoule bottle (glass)

**MA 362 983-3:** 10 ml - 10 units pack - Not Reimbursed by French Health Care Security – Approved for institutions.

### Hospital Packaging:

#### Ampoule bottle (glass)

**MA 564 780-6:** 10 ml - 100 units pack - Approved for institutions.

## HOW SUPPLIED

Not applicable.

## DATE OF REVISION

February 2004

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