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

QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>SPECIALTY DOSE</th>
<th>1 g/10 ml</th>
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<tbody>
<tr>
<td>MAGNESIUM CHLORIDE HEXAHYDRATE</td>
<td>1.0 g</td>
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<tr>
<td>Corresponding quantity in magnesium element</td>
<td>0.12 g</td>
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<tr>
<td>Water for injectable solutions</td>
<td>s.q 10 ml</td>
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</tbody>
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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.

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

Interactions with other drugs and other forms of interactions
Contraindicated interactions:
- Quinidines: 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