

LAVOISIER (Sulfate of) MAGNESIUM 15 %, IV injectable solution

LAVOISIER (SULFATE OF) MAGNESIUM 15 % (1,5 g/10 ml), (I.V.) injectable solution

LAVOISIER (SULFATE OF) MAGNESIUM 15 % (3 g/20 ml), (I.V.) injectable solution

QUALITATIVE AND QUANTITATIVE COMPOSITION

SPECIALTY DOSE	1.5g/10ml	3g/20ml
MAGNESIUM SULFATE Magnesium salt	1.50 g	3.00 g
Water for injectable preparations s.q.	10 ml	20 ml
Equivalence in magnesium (mg/ampoule)	147.90 mg/10 ml	295.80 mg/20 ml
Equivalence in magnesium (mmol/ampoule)	6.088 mmol/10 ml	12.176 mmol/20 ml
	in each 10ml ampoule	in each 20ml ampoule

Total osmolarity: 1 218 mOsmol/l

PHARMACEUTICAL FORM

I.V. injectable solution

THERAPEUTIC INDICATIONS

- Curative treatment of torsades de pointe (TdP)
- Treatment of acute hypokalaemia 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. 2 g of magnesium sulfate in slow intravenous injection, followed by continuous infusion from 0.012 to 0.08 mmol of magnesium cation per minute, i.e. 3 to 20 mg/minute of magnesium sulfate.

Treatment of acute hypokalaemia associated with hypomagnesemia:

Intravenous infusion from 24 to 32 mmol of magnesium cation, i.e. 6 to 8 g of magnesium sulfate by 24 hours. Potassium supplementation must be dispensed from a container different from that of magnesium.

Treatment discontinuation once magnesium levels return to normal.

Magnesium supplementation in electrolyte rebalance and parenteral nutrition:

Intravenous infusion from 6 to 8 mmol of magnesium cation by 24 hours, i.e. 1.5 to 2 g of magnesium sulfate.

In children, the usual posology is 0.1 to 0.3 mmol/kg of magnesium cation, i.e., 25 to 75 mg/kg by 24 hours.

Preventive and curative treatment of eclampsia crisis:

To prevent eclampsia or when it occurs, administer an intravenous infusion in 16 mmol of magnesium cation, i.e. 4 g of magnesium sulfate from 20 to 30 minutes.

If eclampsia persists, repeat intravenous infusion in 16 mmol of Mg⁺⁺ (i.e. 4 g of magnesium sulfate) not exceeding the maximal cumulated dose in 32 mmol of magnesium cation (i.e. 8 g of magnesium sulfate) in the first hour of treatment.

Afterward continuous infusion from 8 to 12 mmol of magnesium cation (i.e. 2 to 3 g of magnesium sulfate) per hour for the 24 hours following the last attack.

Administration:

- Slow intravenous injection
- In venous infusion, diluted in glucose or saline solution

CONTRA-INDICATIONS

This drug is contraindicated in patients with severe renal failure (creatinine clearance under 30 ml/min/1.73 m²).

In general this drug should not be coadministered with quinidines (see section on Interactions with other drugs and other forms of interactions).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

HYPERTONIC SOLUTION TO BE INJECTED SLOWLY.

- The first intravenous injections should be performed at hospital.
- Infusion rate should not be exceeding 0.6 mmol magnesium cation per minute, i.e. 150 mg/minute magnesium sulfate 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:

- **Quinidines:** Increase of plasma concentrations of quinidine with risk of overdosage (decreased renal excretion of quinidine by alkalization of urines).

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 consequences of an exposure in pregnancy.

Consequently, magnesium should be used in pregnancy only if absolutely necessary. In the absence of data, breast-feeding should be avoided.

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.
- IV Injection of 1 g of calcium gluconate
- Hemodialysis or peritoneal dialysis in patients with renal insufficiency.

CLINICAL PHARMACOLOGY

Pharmacodynamics

MAGNESIUM SALTS SOLUTION

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, hypoparathyroidy),
 - . excessivel increase of renal losses (tubulopathies, severe polyurias, diuretics abuse, chronic pyelonephritis, primary hyperaldosteronism, treatment with cisplatin)

Pharmacokinetics

Urinary excretion mainly.

PHARMACEUTICAL DATA

Incompatibilities

- Complexation with EDTA
- Precipitates may form with:
 - ♦ alkaline phosphates
 - ♦ carbonates, bicarbonates and hydroxides
 - ♦ tartrates, salicylates
 - ♦ procaine

Shelf life

5 years

Nature and contents of container

10 ml ampoule bottle (type I glass); 10 or 100 units pack
20 ml ampoule bottle (type I glass); 10 or 50 units pack

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging:

Ampoule bottle (glass)

MA 362 998-0: 10 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for institutions.

MA 362 999-7: 20 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for institutions.

Hospital Packaging:

Ampoule bottle (glass)

MA 564 781-2: 10 ml - 100 units pack - Approved for institutions.

MA 564 782-9: 20 ml - 50 units pack - Approved for institutions.

HOW SUPPLIED

Not applicable.

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