LAVOISIER Hypertonic SODIUM CHLORIDE 10 % - 20 %, injectable solution to be diluted

QUALITATIVE AND QUANTITATIVE COMPOSITION

CONCENTRATION	**10 %**	**20 %**
Sodium chloride	10.0 g	20.0 g
Water for injectable preparations s.q.	100 ml	100 ml
Sodium	171.1 mmol/100 ml	342.2 mmol/100 ml
Chlorides	171.1 mmol/100 ml	342.2 mmol/100 ml
Osmolarity	3.42 Osm/l.	6.84 Osm/l.

pH ranging from 4.5 to 7.0

PHARMACEUTICAL FORM
Injectable solution to be diluted

THERAPEUTIC INDICATIONS
- Electrolyte rebalance when small supplemention of water is desired, in slow intravenous infusion.
- Sodium supplementation with reduced volume in solutions for parenteral nutrition.

POSOLOGY AND ADMINISTRATION
Posology depends on patient's weight, clinical state and laboratory results.
By intravenous route, to be diluted prior to use.
1 g of sodium chloride corresponds to 17 mmol of sodium ion.

CONTRA-INDICATIONS
All the states of sodium retention and particularly:
- Cardiac insufficiency
- oedemato-ascitic syndrome in cirrhotics.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
- Verify physical integrity of container.
- Inspect for limpidity of the solution.
- This drug should be administered with caution in patients with cardiac insufficiency, peripheral or pulmonary oedemas, severe renal impairment.
- In neonates and elderly patients, administration of the product requires to be closely monitored.
- This therapy must be performed under strict medical monitoring, with posology adjustment depending on the results of electrolyte assessments.
- The solution being hypertonic, sodium rebalance should be performed slowly.

ADVERSE REACTION
- Risk of pulmonary and peripheral oedema if perfusion rate is too fast and/or infusion too profuse.
- If not properly diluted, pain may occur at injection site and venous irritation.

OVERDOSAGE
- Nausea, vomiting, diarrhoea, intense thirst, sweating, fever, hypotension and tachycardia, renal failure, peripheral and pulmonary oedema, agitation, irritability, convulsions then coma.
- Overuse of chloride may cause bicarbonate deficiency and result in acidosis.
- Treatment is symptomatic: electrolyte rebalance and administration of diazepam in case of convulsions.

PHARMACOLOGICAL PROPERTIES
HYPERTONIC SODIUM SUPPLEMENT
(B: Hematopoietic stem cells blood and lymphoid organs).
Parenteral solution to rebalance ions blood flow.
The properties are similar to sodium and chloride ions.

PHARMACEUTICAL DATA

Incompatibilities
- Inspect for possible discoloration and/or formation of precipitate, insoluble complex or crystals.
- Prior to any drug admixture, check whether its pH space efficacy matches that of sodium chloride 10% or 20% solution.
- When a drug is added to this solution, admixture should be dispensed instantly.

Shelf life: 5 years

Nature and contents of container
5 ml, 10 ml or 20 ml ampoule, (type I glass), available in 10, 50 or 100 units pack.

PACKAGING AND PRODUCT LICENSE NUMBER

Pharmacy Packaging: Ampoule (glass)

Sodium chloride 10%
MA 363 410-7: 10 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for Institutions.
MA 363 411-3: 20 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for Institutions.

Sodium chloride 20%
MA 363 413-6: 10 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for Institutions.
MA 363 414-2: 20 ml - 10 units pack - Not Reimbursed by French Health Care Security - Approved for Institutions.

Hospital Packaging: Ampoule (glass)

Sodium chloride 10%
MA 565 348-0: 10 ml - 100 units pack - Approved for Institutions.
MA 565 349-7: 20 ml - 50 units pack - Approved for Institutions.

Sodium chloride 20%
MA 565 350-5: 10 ml - 100 units pack - Approved for Institutions.
MA 565 351-1: 20 ml - 50 units pack - Approved for Institutions.

HOW SUPPLIED
Not applicable

DATE OF REVISION
February 2004

CDM LAVOISIER
Laboratoires Chaix et Du Marais - 7, rue Labie - 75017 PARIS - FRANCE
Tel: +33 1 55 37 83 83 E-mail: contact@lavoisier.com Fax: +33 1 55 37 83 84