**Lavoisier Hypertonic Sodium Chloride 10% - 20%, injectable solution to be diluted**

### Qualitative and Quantitative Composition

<table>
<thead>
<tr>
<th>Concentration</th>
<th>10%</th>
<th>20%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Chloride</td>
<td>10.0 g</td>
<td>20.0 g</td>
</tr>
<tr>
<td>Water for injectable preparations s.q.</td>
<td>100 ml</td>
<td>100 ml</td>
</tr>
<tr>
<td>Sodium</td>
<td>171.1 mmol/100 ml</td>
<td>342.2 mmol/100 ml</td>
</tr>
<tr>
<td>Chlorides</td>
<td>171.1 mmol/100 ml</td>
<td>342.2 mmol/100 ml</td>
</tr>
<tr>
<td>Osmolarity</td>
<td>3.42 Osm/l.</td>
<td>6.84 Osm/l.</td>
</tr>
</tbody>
</table>

pH ranging from 4.5 to 7.0

### Pharmaceutical Form

Injectable solution to be diluted

### Therapeutic Indications

- Electrolyte rebalance when small supplementation 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
- Oedema-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 proffuse.
- 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.

### Pharmacological 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.

- Sodium chloride 20%  
  MA 363 413-6: 10 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