

# LAVOISIER SODIUM CHLORIDE 0.9 %, injectable solution

## QUALITATIVE AND QUANTITATIVE COMPOSITION

**SODIUM CHLORIDE** ..... 0.9 g  
Water for injectable preparations ..... s.q ..... 100 ml  
in each 100 ml of injectable solution  
Sodium: ..... 15.4 mmol/100 ml  
Chlorides: ..... 15.4 mmol/100 ml  
Osmolarity: ..... 308 mOsm/l  
pH ranging from 4.5 to 7

## PHARMACEUTICAL FORM

Injectable solution

## THERAPEUTIC INDICATIONS

- Rebalance of ions with sodium and chloride supplements.
- Extracellular dehydration.
- Vehicle for therapeutic supplementation.
- Hypovolemia.

## POSOLOGY AND ADMINISTRATION

Injectable route.

As suggested indication for adults, depending on patient's weight and state: from 500 ml to 3000 ml by 24 hours.

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.

## WARNINGS

### For bottles:

- Verify physical integrity of container and its closures
- Inspect for limpidity of the solution
- Cleanse stopper.

### For ampoules:

- Verify physical integrity of container
- Inspect for limpidity of the solution

## CLINICAL PHARMACOLOGY

### ISOTONIC SODIUM SUPPLEMENTATION

(B: hematopoietic stem cells blood and lymphoid organs).

Parenteral solution to rebalance ions blood flow. The properties are those of 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 0.9% solution.
- When a drug is added to this solution, admixture should be dispensed instantly.

### Shelf life

- Ampoules and bottles (glass): 5 years
- Bottles (Polyethylene) and ampoules (polypropylene): 3 years
- Bag (PVC): 27 months

### Special precautions for storage

- Ampoules (glass and polypropylene) and (glass and polyethylene) bottles: no special storage precautions required
- Bag (PVC): to be stored at controlled temperature not exceeding 25°C (77°F)

### Nature and contents of container

- 125 ml, 250 ml, 500 ml or 1000 ml bottles (type II glass), closed with a chlorobutyl stopper; 1, 6, 12 or 24 units pack.
- 2 ml, 5 ml, 10 ml or 20 ml ampoule, colorless glass (type I); 10, 50 or 100 units pack.
- Vinyl polychloride plasticized bags closed with a makrolon stopper (polycarbonate of bisphenol A), available in 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml or 2000 ml overwrap; 1, 4, 5, 6, 10, 20, 30 or 50 units pack.
- Polyéthylene bottles of 100ml, 250ml, 500 ml, 1000 ml
- Polypropylene ampoules: 5ml, 10 ml, 20 ml

### Instructions for use, Drug handling instruction

- Remove the pouch from the overwrap, inspect for limpidity and physical integrity of container.
- For drug addition, inject into the syringe through the site of injection.
- To reconstitute powders, a double-needle transfer set must be used.
- Puncture the trocar access.
- Place the adequate intravenous line after initial puncture of the trocar, purge the intravenous line. Regulate the perfusion flow rate.

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging:

#### Ampoule (glass)

- MA 363 404-7:** 2 ml - 10 units pack - Approved for Institutions  
**MA 363 405-3:** 5 ml - 10 units pack - Approved for Institutions  
**MA 363 407-6:** 10 ml - 10 units pack - Approved for Institutions  
**MA 363 408-2:** 20 ml - 10 units pack - Approved for Institutions

#### Bottle (glass)

- MA 305 784-5:** 125 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.46 €  
**MA 305 789-7:** 250 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.51 €  
**MA 305 794-0:** 500 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.86 €  
**MA 305 783-9:** 1000 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 3.61 €

#### Overwrap Bag (PVC)

- MA 354 702-9:** 50 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.19 € - Approved for Institutions  
**MA 354 705-8:** 100 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.43 € - Approved for Institutions  
**MA 354 708-7:** 250 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.49 € - Approved for Institutions  
**MA 354 712-4:** 500 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.86 € - Approved for Institutions  
**MA 354 717-6:** 1000 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 3.61 € - Approved for Institutions

#### Bottles (Polyethylene)

- MA 390 770-0:** 100 ml – 1 unit pack  
**MA 390 772-3:** 250 ml – 1 unit pack  
**MA 390 775-2:** 500 ml – 1 unit pack  
**MA 390 777-5:** 1000 ml – 1 unit pack

#### Ampoules (Polypropylène)

- MA 395 340 4 :** 5 ml ampoule (polypropylene) – 10 units pack  
**MA 395 233 3 :** 10 ml ampoule (polypropylene) – 10 units pack  
**MA 395 235 6 :** 20 ml ampoule (polypropylene) – 10 units pack

### Hospital Packaging:

#### Ampoule (glass)

- MA 363 404-7:** 2 ml - 10 units pack - Approved for Institutions  
**MA 565 344-5:** 5 ml - 100 units pack - Approved for Institutions  
**MA 565 345-1:** 10 ml - 100 units pack - Approved for Institutions

- MA 565 346-8:** 20 ml - 50 units pack - Approved for Institutions

#### Bottle (glass)

- MA 555 797-7:** 50 ml in bottle of 125 ml – 24 units pack - Approved for Institutions  
**MA 555 798-3:** 100 ml in bottle of 125 ml – 24 units pack - Approved for Institutions  
**MA 553 513-1:** 125 ml - 24 units pack - Approved for Institutions  
**MA 553 512-5:** 250 ml - 12 units pack - Approved for Institutions  
**MA 553 511-9:** 500 ml - 12 units pack - Approved for Institutions  
**MA 553 510-2:** 1000 ml - 6 units pack - Approved for Institutions

#### Overwrap Bag (PVC)

- MA 562 848-2:** 50 ml - 50 units pack  
**MA 562 849-9:** 100 ml - 50 units pack  
**MA 572 089-7:** 250 ml - 20 units pack  
**MA 562 851-3:** 500 ml - 20 units pack  
**MA 562 853-6:** 1000 ml - 10 units pack

#### Bottle (Polyethylene)

- MA 390 771-7:** 100 ml – 10 units pack - Approved for Institutions  
**MA 390 774-6:** 250 ml – 10 units pack - Approved for Institutions  
**MA 390 776-9:** 500 ml – 10 units pack - Approved for Institutions  
**MA 390 778-1:** 1000 ml – 10 units pack - Approved for Institutions

#### Ampoules (Polypropylène)

- MA 575 456 0 :** 5 ml ampoule (polypropylene) – 100 units pack  
**MA 575 420 6 :** 10 ml ampoule (polypropylene) – 100 units pack  
**MA 395 236 2 :** 20 ml ampoule (polypropylene) – 50 units pack

### HOW SUPPLIED

Not applicable.

### DATE OF REVISION

June 2009

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