

# 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  
 Osmolality: ..... 308 mOsm/l  
 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.

## PHARMACOLOGY AND ADMINISTRATION

Injectable route.  
 Suggested indication for adults, depending on patient's weight and state: from 500 ml to 3000 ml by hours.  
 The amount of sodium chloride corresponds to 17 mmol of sodium ion.

## CONTRA-INDICATIONS

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 makroilon stopper (polycarbonate of bisphenol available in 50 ml, 100 ml, 250 ml, 500 ml, 1000 ml or 2000 ml overwrap; 1, 4, 5, 6, 10, 20 or 50 units pack.
- Polyethylene 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)**

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

**ottle (glass)**

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

**erwrap Bag (PVC)**

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

**ottles (Polyethylene)**

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

**mpoules (Polypropylène)**

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

**ospital Packaging:**

**mpoule (glass)**

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

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