

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.

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