

LAVOISIER SODIUM CHLORIDE 0.9 %, injectable solution

QUALITATIVE AND QUANTITATIVE COMPOSITION

DIUM CHLORIDE 0.9 g
 per for injectable preparations s.q 100 ml
 in each 100 ml of injectable solution
 mium: 15.4 mmol/100 ml
 orides: 15.4 mmol/100 ml
 nolarity: 308 mOsm/l
 ranging from 4.5 to 7

ARMACEUTICAL FORM

ctable solution

ERAPEUTIC INDICATIONS

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

SOLOGY AND ADMINISTRATION

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

NTRA-INDICATIONS

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

ARNINGS

bottles:

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

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.
- 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.

CKAGING AND PRODUCT LICENSE NUMBER

armacy Packaging:

mpoule (glass)

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

ttle (glass)

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

erwrap Bag (PVC)

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

ttles (Polyethylene)

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

mpoules (Polypropylène)

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

spital Packaging:

mpoule (glass)

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

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