

# LAVOISIER GLUCOSE 5 %, IV injectable solution

## QUALITATIVE AND QUANTITATIVE COMPOSITION

GLUCOSE MONOHYDRATE ..... 5.5 g  
(corresponding quantity in anhydrous glucose ..... 5 g)  
Water for injectable preparations ..... s.q ..... 100 ml  
in each 100 ml of injectable solution

Osmolarity: 27.8 mOsm/100 ml  
Caloric Glucose intake: 200 Kcal/l  
pH ranging from 3.5 to 6.5

## PHARMACEUTICAL FORM

Injectable solution I.V.

## THERAPEUTIC INDICATIONS

- Rehydration in case water loss is higher than sodium chloride and other osmoles loss.
- Prevention against intra and extra cellular dehydration.
- Vehicle for therapeutic supplementation in immediate pre-operative, operative and post-operative periods.
- Prophylaxis and treatment of ketosis in undernutrition.

## POSODOLOGY AND ADMINISTRATION

Parenteral route. Injection or intravenous infusion.

Depending on patient's clinical state, 500 to 3000 ml by 24 hours according to weight, diet and possible supplemental treatments.

## CONTRA-INDICATIONS

Fluid imbalance.

## WARNINGS

- Infusion or intravenous injection must be performed slowly because of the potential for unfavorable osmotic diuresis,
- Verify physical integrity of container and possibly its closures (vial),
- Inspect for limpidity of the solution,
- Cleanse vial stopper.

## SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

- Clinical evaluation and laboratory determinations should be performed including sodium balance, glycosuria and ketonemia, potassium, phosphoremia and glycemia.
- If needed, supplement parenteral nutrition of insulin and potassium.
- In diabetics, glycemia and glycosuria should be monitored and insulin posology be adjusted if needed
- Do not administer blood concomitantly using the same intravenous set because of the potential for pseudo-agglutination.

## INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Do not use additive drug in the container prior to checking compatibility in solution and with container.

## CLINICAL PHARMACOLOGY

GLUCOSE SUPPLEMENT PRODUCT (B: hematopoietic stem cells blood and lymphoid organs). This drug metabolism and pharmacological properties are similar to those seen in glucose. 10 ml of solution provides 2.8 millimoles of glucose, i.e. 2 Kcal.

## PHARMACEUTICAL DATA

### Incompatibilities

- Inspect for discoloration and/or formation of precipitate, insoluble complex or crystals.
- Prior to any drug admixture, check whether its pH space efficacy matches that of glucose 5 % solution.
- When a drug is added to this solution, admixture should be dispensed immediately.

### Shelf life

Vials and ampoules (colorless glass): 5 years.  
Bag (PVC): 2 years.

### Storage special precautions

No storage special precautions required.

### Nature and contents of container

- 125 ml, 250 ml, 500 ml or 1000 ml vials (type II glass), closed with a chlorobutyl stopper.
- Plasticized pouch (vinyl polychloride), rubber stoppered with a makrolon seal (bisphenol A polycarbonate), available in 50 ml, 100 ml, 250 ml, 500 ml or 1000 ml, overwrap.
- 10 ml or 20 ml ampoule bottle (type I glass).

### Safety and drug handling instructions

- 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 and lyophilization, use a double-needle transfer set.
- To puncture the trocar access, remove the tear-open part of the right-hand blade simply by rotating.
- Place the adequate intravenous set after initial puncture of the trocar, purge the perfusion line. Regulate the perfusion flow rate.

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging:

#### Ampoule bottle (glass)

**MA 362 992-2:** 10 ml - 10 units pack - Reimbursed by French Health Care Security 65% - Public Price including VAT: 2,96 €

**MA 362 993-9:** 20 ml - 10 units pack - Reimbursed by French Health Care Security 65% - Public Price including VAT: 4,12 €

#### Vial (glass)

**MA 305 859-5:** 125 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,51 € - Approved for institutions

**MA 305 863-2:** 250 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,57 € - Approved for institutions

**MA 305 865-5:** 500 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT 2,89 € - Approved for institutions

**MA 305 858-9:** 1000 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 3,72 € - Approved for institutions

#### Overwrap Bag (PVC)

**MA 354 251-7:** 50 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,19 € - Approved for institutions

**MA 354 255-2:** 100 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,43 € - Approved for institutions

**MA 354 258-1:** 250 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,57 € - Approved for institutions

**MA 354 262-9:** 500 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,89 € - Approved for institutions

**MA 354 266-4:** 1000 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 3,68 € - Approved for institutions

### Hospital Packaging:

#### Ampoule bottle (glass)

**MA 564 774-6:** 10 ml - 100 units pack - Approved for institutions

**MA 564 775-2:** 20 ml - 50 units pack - Approved for institutions

#### Vial (glass)

**MA 555 795-4:** 50 ml - 125 ml bottle - 24 units pack

**MA 555 796-0:** 100 ml - 125 ml bottle - 24 units pack

**MA 553 491-8:** 125 ml - 24 units pack - Approved for institutions

**MA 553 490-1:** 250 ml - 12 units pack - Approved for institutions

**MA 553 489-3:** 500 ml - 12 units pack - Approved for institutions

**MA 553 488-7:** 1000 ml - 6 units pack - Approved for institutions

#### Overwrap Bag (PVC)

**MA 562 454-4:** 50 ml - 50 units pack

**MA 562 455-0:** 100 ml - 50 units pack

**MA 572 088-0:** 250 ml - 20 units pack

**MA 562 457-3:** 500 ml - 20 units pack

**MA 562 459-6:** 1000 ml - 10 units pack

## HOW SUPPLIED

Not applicable.

## DATE OF REVISION

January 2008

### 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](mailto:contact@lavoisier.com)

Fax: +33 1 55 37 83 84