

# LAVOISIER GLUCOSE 10 %, IV injectable solution

## QUALITATIVE AND QUANTITATIVE COMPOSITION

GLUCOSE MONOHYDRATE ..... 11 g  
(corresponding quantity in anhydrous glucose ..... 10 g)  
Water for injectable preparations ..... s.q ..... 100 ml  
in each 100 ml of injectable solution

Osmolarity: 55.5 mOsm/100 ml  
Caloric glucose intake: 400 Kcal/l  
pH ranging from 3.5 to 6.5

## PHARMACEUTICAL FORM

Injectable solution I.V.

## THERAPEUTIC INDICATIONS

- Caloric glucose intake
- 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 denutrition, diarrhoea or vomiting.

## POSOLOGY 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 (bottle),
- Inspect for limpidity of the solution.
- Cleanse bottle 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

### Pharmacodynamics

GLUCOSE SUPPLEMENT PRODUCT (B: hematopoietic stem cells blood and lymphoid organs). This medicine metabolism and pharmacological properties are similar to those seen in glucose. Each liter solution provides 400 Kcal.

## 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 glucose 10 % 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): 3 years.

### Storage special precautions

Vials and ampoules: No storage special precautions required.  
Bag: To be stored at 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.
- 10 ml or 20 ml ampoule bottle (type I glass).
- Pouch (plasticized vinyl polychloride) closed with a makrolon stopper (polycarbonate of bisphenol A), available in 250 ml, 500 ml or 1000 ml overwrap.

### 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 362 994-5:** 10 ml -10 units pack - Not Reimbursed by French Health Care Security - Approved for institutions.

#### Bottle (glass)

**MA 313 982-7:** 250 ml - 1 unit pack - Not Reimbursed by French Health Care Security - Approved for institutions.

**MA 305 841-9:** 500 ml - 1 unit pack - Not Reimbursed by French Health Care Security - Approved for institutions.

**MA 305 842-5:** 1000 ml - 1 unit pack - Not Reimbursed by French Health Care Security - Approved for institutions.

#### Bag (PVC)

**MA 354 676-8:** 250 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,57 € - Approved for institutions.

**MA 354 680-5:** 500 ml - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2,89 € - Approved for institutions.

**MA 354 684-0:** 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 564 776-9:** 10 ml - 100 unit pack - Approved for institutions.

#### Bottle (glass)

**MA 553 543-8:** 250 ml - 12 units pack - Approved for institutions.

**MA 553 542-1:** 500 ml - 12 units pack - Approved for institutions.

**MA 553 541-5:** 1000 ml - 6 units pack - Approved for institutions.

#### Bag (PVC)

**MA 562 479-7:** 250 ml - 30 units pack

**MA 562 480-5:** 500 ml - 20 units pack

**MA 562 481-1:** 1000 ml - 10 units pack

## HOW SUPPLIED

Not applicable.

## DATE OF REVISION

February 2004

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