

LAVOISIER MANNITOL 20 %, solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

MANNITOL20 g
Water for injectable preparations s.q 100 ml
in each 100 ml of solution for infusion
Osmolarity: 1098 mOsm/l
pH ranging from 5.0 to 6.5

PHARMACEUTICAL FORM

Solution for infusion

THERAPEUTIC INDICATIONS

- Reduction of certain cerebral oedemas
- Intraocular pressure reduction

POSOLGY AND ADMINISTRATION

I.V. Infusion.

Adults: infusion rate is 40 drops/minute 250 ml/daily

Children: infusion of 5 ml/kg/day at a rate of 5 to 10 drops/minute

CONTRA-INDICATIONS

This drug is CONTRAINDICATED for use in patients with:

- Pre-existent plasma hyperosmolarity
- Dehydration with intracellular prevalence

This drug is NOT GENERALLY RECOMMENDED for use in patients with:

- Cardiac insufficiency
- Pulmonary oedema

WARNINGS AND PRECAUTIONS FOR USE

Warnings

Hypertonic solution: to be used with caution. Risk of extravenous diffusion.

- infusion rate must be slow and regular (see Dosage).
- in patients with cardiovascular or renal disease, or in repeat perfusions, it is essential that osmolarity, diuresis and sodium balance be monitored including hemodynamic and renal functions.
- the solution being supersaturated, the bottle must be heated in a double boiler until complete dissolution of crystals. Allow then to cool to body temperature prior to use.

Special warnings and precautions for use

- If after a certain time (about 12 hours) of infusion, diuresis is inadequate, treatment will be discontinued.
- Inspect for discoloration and visible particulate matter prior to infusion.
- Discard any bottle with punctured stopper or any unused portion.
- Use strict asepsis for placement of perfusion.
- Dispenser used must be fitted with a filter.
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INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

Do not introduce any additive drug into container without first checking the compatibility in solution and with container.

PREGNANCY AND LACTATION

In normal conditions of use, Mannitol may be prescribed in pregnancy and to lactating mothers, if necessary.

ADVERSE REACTION

- Risk of electrolyte imbalance.
- Risk of nausea, vomiting, cephalgias, dizziness, tachycardia, thoracic pain, dehydration, blurred vision, hypotension or hypertension, mental confusion.
- Risk of extravasation with infiltration oedema.
- Less common cases of anaphylactoids reactions with urticaria.

CLINICAL PHARMACOLOGY

Pharmacodynamics

SOLUTION OF OSMOTIC DIURESIS (B: hematopoietic stem cells blood and limphoid organs)

- Glucose is hardly metabolized, the product is excreted in renal glomeruli and is not absorbed from tubules. It is therefore inevitable that a certain amount of water be eliminated.

The space the product diffuses out corresponds to the volume of extracellular spaces

Pharmacokinetics

Excreted through the kidney as unchanged.

PHARMACEUTICAL DATA

Drug interactions

- 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 LAVOISIER MANNITOL solution 20%.
- When a drug is added to this solution, admixture should be dispensed immediately.

Shelf life: 3 years

Nature and contents of container

250 ml, 500 ml bottles, colorless glass (type II), closed with a chlorobutyl stopper.

Instructions for use, Drug handling instruction

Prior to use, inspect for particulate matter, physical integrity of bottle, closures and vacuum state.

PACKAGING AND PRODUCT LICENSE NUMBER

MA 344 874-1: 500 ml bottle (glass) - 1 unit pack

Not Reimbursed by French Health Care Security

MA 560 729-6: 500 ml bottle (glass) - 12 units pack

HOW SUPPLIED: Not applicable.

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