

# LAVOISIER SODIUM BICARBONATE 1.4 %, solution for infusion

## QUALITATIVE AND QUANTITATIVE COMPOSITION

**SODIUM BICARBONATE**.....1.40 g  
Water for injectable preparations ..... s.q. ....100.00 ml  
in each 100 ml of solution for infusion  
Sodium : 166.6 mmol/l Bicarbonates: 166.6 mmol/l  
Osmolarity : 333 mOsm/l pH ranging from 7.0 to 8.5

## PHARMACEUTICAL FORM

Solution for infusion

## THERAPEUTIC INDICATIONS

Metabolic acidosis  
Poisoning with phenobarbital

## POSOLOGY AND ADMINISTRATION

- IV injection, in slow infusion.
- Posology adjustment according to etiology, patient's state and the extent of acid-base disturbances.
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## CONTRA-INDICATIONS

- Metabolic alkalosis.
- Respiratory acidosis.
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## WARNINGS AND PRECAUTIONS FOR USE

### Warnings

Administration of this solution may aggravate or reveal hypokalemia.  
Since this solution is alkaline, check compatibilities prior to admixture of concurrent drugs for injection and inspect for limpidity and discoloration prior to infusion (see section Interactions with other drugs and other forms of interactions).

### Special warnings and precautions for use

Use with great caution in patients with sodium retention, cardiac insufficiency, edemato-ascitic syndrome in cirrhotics. Electrolyte and acid-base balance in blood must be monitored routinely. Have account of sodium intake. In patients with hypokalemia, a potassium salt may be added.

## INTERACTIONS WITH OTHER DRUGS AND OTHER FORMS OF INTERACTIONS

In case of drug admixtures delivered by IV route, have account of alkaline pH of the solution and presence of sodium and bicarbonate ions.

The most common incompatibilities include:

- . Drugs triggering an acid reaction in solution (hydrochlorates, insulin, etc)
- . Drugs with insoluble form base (alkaloids, antibiotics, etc).

### Association requiring precaution for use:

#### ◆ Quinidines (hydroxyquinidine, quinidine):

Increase of quinidine plasma concentrations and overdose risk (decrease of quinidine excretion through the kidney by alkalization of urine). Clinical supervision, EKG monitoring and possibly quinidine control: if needed posology adjustment during alkalizing treatment and after treatment suspension.

## ADVERSE REACTION

Metabolic alkalosis and hypokalemia in patients with excessive supplementation.  
Risk of sodium overload if inadequate renal or extra-renal sodium elimination.

### Overdosage

Metabolic alkalosis and respiratory depression, hypokalemia, cardiac insufficiency, acute lung oedema.

## CLINICAL PHARMACOLOGY

### Pharmacodynamics

PRODUCT OF ALKALINE CONTENT (B: hematopoietic stem cells blood and lymphoid organs)  
Sodium bicarbonate solution helps control acid-basic balance in plasma.

## 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 bicarbonate 1.4% solution.

### Shelf life: 5 years

### Nature and contents of container

- 10 ml or 20 ml ampoule bottle, colorless glass (type I).
- 250 ml or 500 ml bottle, colorless glass (type II), closed by a chlorobutyl stopper.

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging:

**MA 366 759-0:** 10 ml ampoule bottle - 10 units pack - Approved for institutions

**MA 305 750-3:** 250 ml bottle - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.25 €

**MA 305 752-6:** 500 ml bottle - 1 unit pack - Reimbursed by French Health Care Security 65 % - Public Price including VAT: 2.49 €

### Hospital Packaging:

**MA 363 795-6:** 10 ml ampoule bottle - 100 units pack - Approved for institutions

**MA 363 796-2:** 20 ml ampoule bottle - 50 units pack - Approved for institutions

**MA 553 506-5:** 250 ml bottle, 12 units pack - Approved for institutions

**MA 553 507-1:** 500 ml bottle, 12 units pack - Approved for institutions

## HOW SUPPLIED

Not applicable

## DATE OF REVISION

April 2005

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