

# LAVOISIER PHENOLATED SALINE SOLUTION, injectable solution in vial

## QUALITATIVE AND QUANTITATIVE COMPOSITION

PHENOL.....	0.50 g
SODIUM CHLORIDE.....	0.90 g
Sodium hydroxide.....	s.q. pH.= 7
Water for injectable preparations .....	s.q. 100 ml

## PHARMACEUTICAL FORM

Solution for injectable preparation

## THERAPEUTIC INDICATIONS

Dilution of allergens in allergology

Dilution of vaccines during vaccination tolerance tests

## POSOLOGY AND ADMINISTRATION

- Each vial contains 9 ml of isotonic solvent designed to make a decimal dilution of allergens or vaccines.
- Withdraw with a graduated syringe the amount needed of allergenic extract or vaccine (variable depending on the nature of vaccine) and introduce it into the solvent vial.
- Shake vigorously the dilution thus obtained and, prior to each use, shake the suspension to prevent administration of a highly concentrated product.

**In allergology: Use intradermal injection.**

**In tests of tolerance to vaccination, in patients with allergic pathology: subcutaneous route must be used, particularly with adsorbed vaccines because of possible allergic reactions induced by adsorbent agent.**

## CONTRA-INDICATIONS

This solution must not be used when immunotherapy and vaccination are contraindicated.

## WARNINGS AND PRECAUTIONS FOR USE

### Special warnings and precautions for use

Never to be injected by intravenous route.

### Precautions for use

Check for conformity with prescription in terms of titration of dilution and volume for injection, following prescriber's instructions.

If any error of dilution, therapeutic countermeasures must be instituted to prevent possible complications (anaphylactic shock): injectable corticoids and ampoules of adrenalin should be readily available.

## PREGNANCY AND LACTATION

- No current data are available for a pertinent evaluation of a possible malformative or foetotoxic effects of this product in pregnancy.
- As a safety measure, this product is not then recommended for use in pregnancy.
- This product should not be administered to lactating mothers.

## CLINICAL PHARMACOLOGY

### Pharmacodynamics

DILUANTS FOR ALLERGENS AND VACCINES

(R. Respiratory system)

## PHARMACEUTICAL DATA

### Shelf life

3 years

### Storage special precautions

To be stored in a dark place.

### Nature and contents of container

9 ml vial, colorless glass (type II), closed with an elastomer stopper and aluminum capsule.

### Instructions for use, Drug handling instruction

After dilution of allergen, store vial at controlled temperature between +4 °C and +8 °C.

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging:

**MA 305 880-4:** 9 ml vial - 1 unit pack - Reimbursed by French Health Care Security 65% - Public Price including VAT: 1,83 €

### Hospital Packaging:

**MA 553 526-6:** 9 ml vial - 50 units pack - Approved for Institutions.

## HOW SUPPLIED

Not applicable.

## DATE OF REVISION

April 1997

### CDM LAVOISIER

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