

# LAVOISIER VITAMIN B 12 1000 µg/1 ml, IM injectable solution

## QUALITATIVE AND QUANTITATIVE COMPOSITION

CYANOCOBALAMINE .....	1000 µg
Sodium chloride .....	9 mg
Diluted hydrochloric acid .....	s.q ..... pH 3.8 to 5.5
Water for injectable preparations .....	s.q ..... 1 ml

## PHARMACEUTICAL FORM

Injectable solution

## THERAPEUTIC INDICATIONS

Proven vitamin B12 deficiencies due to the inability of the body to absorb vitamin B: Biermer's disease, total gastrectomy, resection of terminal ileum, disease of Imerslund.

## POSODOLOGY AND ADMINISTRATION

### Intramuscular route.

Not to be injected by I.V. route.

### Intensive treatment:

1 mg (one ampoule) daily or three times a week by I.M. route  
i.e. 10 mg (10 ampoules) in total.

### Maintenance treatment:

1 mg (one ampoule) per month by I.M. route.

## CONTRA-INDICATIONS

- Antecedents of allergy to cobalamines (vitamin B12 and related substances).
- Malignant tumor: because of the action of vitamin B12 on the growth of tissues with high cellular multiplication rate, risk of evolutive eruption should be taken into account.

## ADVERSE REACTION

- Allergic reactions: prurit, urticaria, eczema, erythema, cutaneous necrosis, oedema potentially severe: anaphylactic shock or Quincke's oedema.
- Risk of acne.
- Risk of pain at injection point.
- Red coloration of urines (corresponding to excretion of vitamin B12 in urine).

## OVERDOSAGE

No B12 hypervitaminosis.

## CLINICAL PHARMACOLOGY

### Pharmacodynamics

ANTI-ANEMIC - VITAMIN B12 (B: hematopoietic stem cells blood and lymphoid organs)

Cyanocobalamin: hematopoietic factor.

### Pharmacokinetics

Vitamin B12 is absorbed from the terminal ileum via two mechanisms:

- a passive mechanism when levels are high,
- and an active mechanism triggering the absorption of physiological doses, the intrinsic factor being present is then essential.

Serum peak is reached within an hour after intramuscular injection.

The major excretion path is through urine.

## PHARMACEUTICAL DATA

**Shelf life:** 3 years

### Special precautions for storage

To be stored in a dark place.

### Nature and contents of container

1 ml ampoule bottle, colorless glass (type I), self-breakable.

## PACKAGING AND PRODUCT LICENSE NUMBER

### Pharmacy Packaging: Ampoule bottle (glass)

**MA 355 153-9:** 1 ml - 10 units pack - Not Reimbursed by French Health Care Security.

### Hospital Packaging: Ampoule bottle (glass)

**PL 562 856-5:** 1 ml - 100 units pack - Approved for Institutions.

## HOW SUPPLIED

Not applicable

## DATE OF REVISION

August 2000

### CDM LAVOISIER

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