LAVOISIER VITAMIN B12 1000 µg/1 ml, IM injectable solution

QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyanocobalamin</td>
<td>1000 µg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>9 mg</td>
</tr>
<tr>
<td>Diluted hydrochloric acid</td>
<td>q.s. pH 3.8 to 5.5</td>
</tr>
<tr>
<td>Water for injection</td>
<td>q.s. 1 ml</td>
</tr>
</tbody>
</table>

Excipient with known effect: sodium

PHARMACEUTICAL FORM
Injectable solution IM

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

POSOLOGY AND ADMINISTRATION

Intramuscular route:
Not to be injected by I.V. route.
Induction 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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
A haematological and neurological monitoring must be performed during the treatment.

The kaliemia should be closely monitored during the first two days of treatment with vitamin B12 in megaloblastic anemia: a hypokaliemia could occur due to the increase of erythrocytes needs in potassium.

In case of lack of therapeutic response following vitamin B12 administration in patients with megaloblastic anemia, the diagnosis of a deficiency of the folic acid metabolism should be considered. Daily doses higher than 10µg can lead to hematological answer in patients with a folic acid deficiency. An administration without prior distinction of the deficiency risks to false an accurate diagnosis.

This medicine contains sodium. The level of sodium is less than 1mmol per dose, ie “sodium free”.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Interactions to be considered

+ Chloramphénicol
Concomitant administration of chloramphenicol may decrease the therapeutic hematologic effect of vitamin B12 in anemic patients. Simultaneous administration of both products require specific monitoring.

+ Methotrexate, pyrimethamine and the most of antibiotics
Risk of interference with microbiological diagnostic tests for vitamin B12 deficiency.

PREGNANCY AND LACTATION
The use of this medicine in pregnant or breastfeeding woman is possible based on available data.

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
Pharmacotherapeutic class: ANTIANEMIC - VITAMIN B12 (B: hematopoietic stem cells blood and lymphoid organs)
Cyanocobalamine: 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

Incompatibilities
In the absence of compatibility studies, this medicine must not be mixed with other medicines.

Shelf life
3 years
Following opening: the product should be used immediately.

Special precautions for storage
To be stored protected from light.

Nature and contents of container
1 ml ampoule bottle, colorless glass (type I), self-breakable.

MARKETING AUTORISATION HOLDER
Laboratoires CHAIX et DU MARAIS

PRESENTATIONS AND PRODUCT LICENSE NUMBERS

Pharmacy Packaging: Ampoule bottle (glass)
MA 3400935515391: 1 ml - 10 units pack - Not Reimbursed by French Health Care Security.

Hospital Packaging: Ampoule bottle (glass)
MA 3400956285655: 1 ml - 100 units pack - Approved for Institutions.

DATE OF REVISION
February 2012

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