VITAMINE B6 STEROP solution for injection is a group B vitamin which is soluble in water.

This medicine is prescribed for:
- The prevention and treatment of confirmed vitamin B6 deficiencies caused by malnutrition, certain conditions or the treatment with certain medicines (for example, isoniazid, penicillamine and immunosuppressants).
- Conditions for which the recommended treatment consists of administration of vitamin B6, including certain genetic conditions or specific types of convulsions in children.
- Intravenous administration of vitamin B6 has been shown to be effective for the treatment of acute symptoms of isoniazid poisoning (intoxication), particularly for the treatment of convulsions, increased acidity in the blood (acidosis) and coma.
- Vitamin B6 has also been used as an adjunctive treatment for acute cycloserine, hydrazine and Gyromitra (a fungus whose toxins release methylhydrazine) poisoning.

You must talk to a doctor if you do not feel better or if you feel worse after a few days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VITAMINE B6 STEROP

Do not use VITAMINE B6 STEROP
- If you are allergic to vitamin B6.
If you are also taking levodopa alone because vitamin B6 reduces the activity of levodopa when it is not combined with drugs which are called "dopa decarboxylase" inhibitors.

If the solution is not clear.

**Warnings and precautions**

- Considering the risk of intense calming effect (excessive sedation), when vitamin B6 is administered to diagnose or to treat convulsions in new born babies, a fully equipped crash cart must be available.
- Prolonged treatment and/or the administration of high doses of vitamin B6 may cause serious neurotoxic disorders.

If you take already other drugs, read also the section “Other medicines and VITAMINE B6 STEROP”.

**Other medicines and VITAMINE B6 STEROP**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Immunosuppressants (medicines which decrease the body's immune response), isoniazid (anti-tuberculosis medicine), penicillamine (medicine used notably to treat rheumatoid arthritis) and oral contraceptives can reduce the effects of pyridoxine (vitamin B6) directly or increase its excretion in the urine, thus causing anaemia or inflammation of the peripheral nerves (= neuritis). It may therefore be recommended to increase the vitamin B6 supplement dose taken if you are also taking these medicines.
- Taking even small doses (± 5mg) of pyridoxine (vitamin B6) at the same time as levodopa (an anti-Parkinson's disease drug) alone speeds up the breakdown of levodopa in the body which means that it becomes less effective. This combination is therefore contraindicated unless you are also taking an additional medicine (one in the dopa decarboxylase inhibitor group) aimed at preventing the breakdown of levodopa.
- Vitamin B6 treatment may decrease the amount of phenobarbital (barbiturate medicine prescribed for the prevention of epilepsy) and phenytoin in the blood when these treatments are administered concomitantly.

**VITAMINE B6 STEROP with food, drink and alcohol**

Not applicable.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Pregnancy**

Pyridoxine (vitamin B6) crosses the placenta barrier. No harmful effects have been reported in humans taking the normal recommended daily doses. However, foetuses exposed to high doses of pyridoxine (vitamin B6) in the womb (in utero) may present a dependence syndrome (with convulsions) at birth.

**Breast-feeding**

Vitamin B6 is excreted in the breast milk. However, no harmful effects have been reported in patients taking the normal recommended daily doses.

**Fertility**

No data available

**Driving and using machines**
No effects on the ability to drive vehicles or operate machinery have been reported to date.

3. HOW TO USE VITAMINE B6 STEROP

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

VITAMIN B6 STEROP must be administered by intramuscular (IM) or intravenous route (IV). The recommended doses vary depending upon the effect sought and the age of the patient.

**Adult dose**

There is no precise indication for the IV or IM administration of vitamin B6 in adults. The oral route should be preferentially selected to treat conditions that respond to vitamin B6 therapy and vitamin B6 deficiencies (induced by certain medicines and other deficiencies). However, the IV and IM routes may also be used.

The IV and IM dosages of Vitamin B6 vary according to the condition requiring treatment and are as follows:

- **Vitamin B6 deficiencies:**
  The recommended dose is 5 to 25mg/day via IM or IV for three weeks, followed by a maintenance dose of 1.5 to 5mg/day (using an oral form wherever feasible).

- **Conditions responding to vitamin B6 treatment:**
  Irrespective of the route of administration: 10 to 250mg/day. Higher doses (up to 600mg/day) can be necessary in some cases.
  If the patient responds to treatment, the dose can be switched to 30mg/day (preferably using the oral form).

- **Adjunctive therapy for the treatment of acute symptoms of poisoning:**
  To treat convulsions and/or coma caused by acute isoniazid poisoning, a dose of vitamin B6 equivalent to the dose of isoniazid ingested is generally recommended, to be given together with other anti-seizure drugs if necessary. In general, 1 to 4 g of vitamin B6 is administered by the IV route, followed by 1g via IM route every 30 minutes, until the entire dose has been administered.
  To treat a cycloserine poisoning, a daily dose of 300mg of vitamin B6 is recommended.
  To treat an acute hydrazine poisoning, a daily dose of 25mg/kg of vitamin B6 is recommended. One third of this dose is administered by IM route, whilst the remainder is administered by IV infusion (after dilution in 0.9% saline solution) over 3 hours.
  It has been suggested that the neurological effects caused by ingestion of Gyromitra (a fungus whose toxins release methylhydrazine) can be treated with injection of vitamin B6 at a dose of 25mg/kg by IV infusion (after dilution in 0.9% saline solution) administered over 15 to 30 minutes, to be repeated if necessary, up to a maximum cumulative dose of 15 to 20 g per day. If diazepam is administered concomitantly, lower doses of vitamin B6 can effectively control the convulsions.

**Dose in children**
• Conditions responding to vitamin B6 treatment:
  In children, the recommended dose of vitamin B6 for the treatment of conditions responding to vitamin B6 therapy is 10 to 250mg/day by the IM or IV route (wherever possible, the oral route should be used). The recommended dose for young children is 2 to 15mg/day via IM or IV route.

  Doses of Vitamin B6 ranging from 100 to 200mg via IV have been suggested as an emergency treatment for children with convulsions that are alleviated by vitamin B6 (these are extremely rare but should be suspected in children with convulsions that otherwise appear to be untreatable); however, these doses cannot be recommended owing to the risk of respiratory depression (or failure) in new born babies. If a clear response to treatment is observed, it is preferable to switch to the oral route (at a dose of 2 to 200mg/day).

  Note: Because vitamin B6 therapy can have an extremely calming effect, a full equipped crash cart must be kept close by when pyridoxine (vitamin B6) is administered to diagnose or to treat convulsions in new born babies.

• Vitamin B6 deficiencies:
  Most vitamin requirements are met by the diet. However, if an "overall" vitamin deficiency is suspected, the optimal treatment should be based around a combined vitamin supplement and, above all, adjust the diet accordingly.

  A treatment with vitamin B6 alone is considered acceptable only for rare cases of specific deficiencies.

  In such cases, the vitamin B6 dose recommended for children is 5 to 25mg/day, preferably by the oral route, for three weeks and followed by a 1.5 to 2.5mg/day maintenance dose, in a multivitamin preparation. However, the IV and IM routes may also be used.

Note for nursing staff
• VITAMINE B6 STEROP does not contain any antimicrobial preservatives and may therefore encourage microbial growth. Before administration, immediately after the ampoule is opened, draw the solution into a sterile syringe taking care to ensure that it is not contaminated and following good clinical practice regulations. Once it has been drawn into the syringe, the solution must be used immediately.

  The medicinal solution and any syringe into which it is drawn are to be used once, for a single patient. All the remaining unused medicinal solution and the materials in which it is contained must be disposed of in compliance with current good clinical practice recommendations.

  When intramuscular administration, before injecting the dose, aspirate to ensure that the needle is not located in a blood vessel. If blood is aspirated into the syringe, withdraw the needle and choose another injection site. In the event of repeated injections, the injection site should be changed regularly.

  If the solution is administered in an infusion, both the medicinal solution and the infusion kit must be maintained under sterile conditions throughout the infusion in compliance with good clinical practice recommendations. It is good clinical practice to use any prepared medicinal solutions intended for parenteral administration within 24 hours.

  Generally, if administered too quickly or in too high a volume of liquid, the solution may cause irritation or necrosis (destruction of cells) at the injection site or thrombophlebitis (inflammation of the vein after a blood clot forms).

  A blood clot may partially or completely block blood circulation in the affected vein. The injection site should be changed every 24 hours to reduce the risk of thrombophlebitis.

  If high volumes of fluid are administered, check regularly the ionic balance.
**Treatment duration**
Your doctor will tell you how long you should use VITAMINE B6 STEROP for. Please follow his instructions.

**If you use more VITAMINE B6 STEROP than you should**
If you used too much VITAMINE B6 STEROP, contact immediately your doctor, your pharmacist or the Poison center (070/245.245).

The daily vitamin B6 requirements are:

<table>
<thead>
<tr>
<th>Age</th>
<th>Daily vitamin B6 requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 12 months</td>
<td>0.4mg</td>
</tr>
<tr>
<td>1 - 3 years</td>
<td>0.7mg</td>
</tr>
<tr>
<td>4 - 6 years</td>
<td>0.9mg</td>
</tr>
<tr>
<td>7 - 10 years</td>
<td>1.1mg</td>
</tr>
<tr>
<td>11 - 14 years</td>
<td>boys: 1.3mg - girls: 1.1mg</td>
</tr>
<tr>
<td>15 - 18 years</td>
<td>boys: 1.5mg - girls: 1.1mg</td>
</tr>
<tr>
<td>Adults males</td>
<td>2.0mg</td>
</tr>
<tr>
<td>Adults females</td>
<td>1.8mg</td>
</tr>
<tr>
<td>+ 60 years</td>
<td>men: 2.0mg - women: 1.8mg</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>1.9mg</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>2.0mg</td>
</tr>
</tbody>
</table>

**Symptoms**

a) **Acute poisoning:**
The toxic dose of vitamin B6 in humans has not been established.
Massive doses may result in sensory nerve cells damage which can be irreversible, weakness, slow bowel function and acute urinary retention.

b) **Chronic poisoning:**
The toxicity caused by intake of high doses for prolonged periods of time presents as sensory nerve cells damage with an unsteady gait and numbness in the limbs.

**Treatment**
The first step to take in the event of an overdose is to stop treatment immediately.
Thereafter, treatment of overdose tends to be mainly supportive.
There is no known antidote for the prevention or treatment of the nervous system damage (sensory neuropathy) caused by acute vitamin B6 intoxication.
Recovery is slow (from several months to a few years).
Patients presenting with neurological signs or symptoms require careful neurological monitoring and stimulation.

**If you forget to take VITAMINE B6 STEROP**
Take it as soon as possible. If it is almost time for your next dose, wait and take your next dose at the usual time but miss the forgotten dose.
Missing a dose should not pose any risk to your health.
Do not take a double dose to make up for a forgotten dose.
If you stop using VITAMINE B6 STEROP
At the end of the treatment, you can simply stop taking your medication without any particular precautions. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Endocrine disorders:
Decreased milk supply has been reported after taking vitamin B6 orally.

Metabolism and nutrition disorders:
Use of high doses of vitamin B6 (500 to 1500mg a day) has caused a drop in folic acid levels in the blood in certain patients.

An increase in certain enzymes which are naturally present in the liver and heart cells has also been reported, indicating that these organs (liver and heart) have been damaged. (enzymes = types of proteins produced by the body that are capable of triggering specific chemical reactions).

Psychiatric disorders:
Memory loss and insomnia have also been reported after oral vitamin B6 treatment.

Nervous system disorders:
Long-term administration of high doses of vitamin B6 has been known to cause neurological side effects [nervous system impairment (Neuropathy), excessive sedative effect, decreased muscle tone (hypotonia) and convulsions].

However, more recent reports also mention cases of neuropathy (with abnormal skin sensations (paraesthesia) and a decrease in proprioception, which is the ability to sense the relative position of the different parts of the body and their movement without actually looking at them) with lower doses (50 to 500mg a day).

In general, neuropathic symptoms tend to persist after treatment is stopped.

Note: Given that there is a risk of deep sedation when vitamin B6 is administered to diagnose or treat convulsions in new born babies, a fully stocked crash cart must be readily available in this instance.

Cases of somnolence have been reported in sensitive individuals treated with doses as low as 5mg per day.

Headaches have also been reported.

Respiratory disorders:
Signs of respiratory distress such as difficulty breathing (dyspnoea) and more or less prolonged breathing pauses (apnoea) which sometimes require respiratory assistance, combined with an intense calming effect (sedation) and a decrease in muscle tone (hypotonia) have been reported after oral or parenteral (i.e. directly into the body, not absorbed through the gastrointestinal tract) administration of vitamin B6 in children with convulsions which can be treated with vitamin B6. According to certain hypotheses, vitamin B6 has a direct sedative effect.

For this reason, it is recommended that a fully stocked crash cart should be readily available when vitamin B6 is administered to diagnose or treat convulsions in new born babies.
**Gastrointestinal disorders:**
Nausea has been reported with therapeutic doses, whilst vomiting, abdominal pain and major loss of appetite (anorexia) have been reported at high doses.

**Skin and subcutaneous tissue disorders:**
Sensitivity to light (photosensitivity) and other allergic reactions:
High doses of vitamin B6 can cause skin lesions which present as blisters and vesicles after exposure to light. A case of fulminant rosacea has also been reported in a patient after she had taken a vitamin B supplement containing a high dose of vitamin B6 for two weeks. (rosacea = a skin condition characterised by redness on the face and exposed parts of the body, with inflammation, suppurating vesicles at the hair roots, and seborrhoea (this is an increase in the secretion of sebum, a natural oil secreted by certain glands in the skin which makes skin and hair look greasy).

Local effects: Some patients may experience burning or stinging at the injection site after intramuscular administration of vitamin B6.

**Other side effects:**
Withdrawal symptoms: Temporary withdrawal symptoms (nervousness, trembling, abnormalities on the electroencephalogram tracing recorded to measure the brain's electrical activity) have been described in some patients after discontinuation of a treatment with vitamin B6. However, these findings have not been confirmed by other studies.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

5. **HOW TO STORE VITAMINE B6 STEROP**
Keep this medicine out of the sight and reach of children.

Keep the ampoules in the outer carton in order to protect from light. Vitamin B6 is indeed light sensitive and will degrade slowly when exposed to light. This medicinal product does not require any special temperature storage conditions.

Do not use this medicine after the expiry date which is stated on the pack after the mention “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

What VITAMINE B6 STEROP contains
The active substance is pyridoxine (or vitamin B6), under the form of pyridoxine hydrochloride 100mg per 2ml or 250mg per 2ml of solution. The other ingredient is water for injections.

What VITAMINE B6 STEROP looks like and contents of the pack
Solution for injection by intramuscular or intravenous route in 2ml glass ampoules. Packaging in boxes of 3, 10 and 100 ampoules.

**Marketing Authorisations**  
VITAMINE B6 STEROP 100mg/2ml : BE271713  
VITAMINE B6 STEROP 250mg/2ml : BE271722

**Prescription** : On medical prescription.

**Marketing Authorisation Holder and Manufacturer**  
LABORATOIRES STEROP - Avenue de Scheut 46-50 - B-1070 Brussels - Belgium.

**This leaflet was last approved in 01/2014**