

PACKAGE LEAFLET: Information for the patient

VITAMINA B6

Tablets – 25 mg

Solution for injection – 100 mg / 2 ml

(Pyridoxine hydrochloride)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Vitamina B6 is and what it is used for
2. Before you take Vitamina B6
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1. WHAT VITAMINA B6 IS AND WHAT IT IS USED FOR

Vitamina B6 (pyridoxine hydrochloride) is a water soluble vitamin. Actually, vitamin B₆ means three similar components: pyridoxine, pyridoxal and pyridoxamine, from which, pyridoxine in the form of hydrochloride is mainly used. Pyridoxine participates mainly in the metabolism of aminoacids, but also in the metabolism of carbohydrates and fats. It is also necessary for the formation of hemoglobin. Pyridoxin deficiency is rare in humans, because it is present in foods, however it may be caused by drugs, such as during treatment with isoniazid. Pyridoxine

deficiency may cause sideroblastic anemia, dermatitis, chielosis, and neurological symptoms, such as peripheral neuritis and convulsions.

Vitamina B6 is indicated in:

- conditions that derive from pyridoxine deficiency;
- isoniazid-induced neuropathy;
- treatment of nausea or vomiting in the period of pregnancy;
- idiopathic sideroblastic anemia;
- hyperoxaluria type I;
- hydrazine toxicity;
- prophylaxis of vomiting by ether.

2. BEFORE YOU TAKE VITAMINA B6

Do not take Vitamina B6 if you are hypersensitive to pyridoxine hydrochloride or to any of the other excipients of the tablet or of the solution for injection.

Intravenous Vitamina B6 administration in patients with cardiac pathology should be avoided.

Take special care with Vitamina B6

Ask your doctor before taking Vitamina B6.

Pyridoxine is excreted with breast milk and may inhibit lactation.

Safety and efficacy of pyridoxine in children in doses which overpass alimentary requests is not yet determined.

Patients who are treated with levodopa should not take Vitamina B6 concomitantly.

This limitation is not necessary if levodopa is associated with a dopa-decarboxylase inhibitor.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Vitamina B6. Please contact with your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Vitamina B6 if you have been given any other drug during treatment.

It is especially important that your doctor be aware of the fact that you are treated with:

- levodopa, because pyridoxine reduces its effects if administered in high doses, but this does not occur if levodopa is associated with a dopa-decarboxylase inhibitor;
- phenobarbital or phenytoin, because pyridoxine reduces their concentrations in serum;
- isoniazid, hydralazine, penicillamine, oral contraceptives, because these drugs may increase the requests for pyridoxine;
- altretamine, because pyridoxine reduces its effect.

Pregnancy

Category C (A).

Vitamina B6 may be administered in amounts which correspond to the daily needs.

Although severe consequences are not known, this drug should not be used during pregnancy, except the case when the potential benefit outweighs the risk to which the fetus is exposed.

Ask for the advice of the pharmacist or doctor before taking this drug!

Breastfeeding

Ask for the advice of the pharmacist or of the doctor before taking this drug!

Vitamin B6 (pyridoxine hydrochloride) is excreted with breast milk and may inhibit lactation.

It should not be used during lactation, except the case when the potential benefit outweighs the risk to which the baby is exposed.

Driving and using machines

There are no data if this drug influences the ability to drive and use machines.

Important information about some of the excipients of Vitamina B6

Vitamina B6 tablets contain lactose. If you have been told by your doctor that you suffer from the intolerance to some sugars, talk to your doctor before taking this drug.

3. HOW TO TAKE VITAMINA B6

Always take Vitamina B6 as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Vitamina B6 are too strong or too weak, talk to your doctor or pharmacist.

The dosage is as follows:

- *in conditions of a vitamin B6 (pyridoxine) deficiency:*

by mouth and by subcutaneous injection: 20 – 50 mg up to 3 times daily;

- *in isoniazid-induced neuropathies:*

by mouth: 12.5 mg daily (prophylaxis); 50 mg, 3 times daily (treatment);

by intramuscular or intravenous or subcutaneous injection: 50 mg up to 200 mg daily;

- *in idiopathic sideroblastic anemia:*

by mouth or by intramuscular or intravenous or subcutaneous injection: 50 – 100 mg daily;

- *in the prophylaxis of vomiting by ether:*

by intramuscular injection: 100 mg, 20 minutes before the beginning of the general anesthesia.

If you take more Vitamina B6

If you take more Vitamina B6 than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Vitamina B6

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Vitamina B6 may cause side effects, although not everybody manifests them.

Most of the side effects are dose-related and disappear when dosage is reduced or treatment is discontinued. Some side effects may happen at the beginning of treatment and disappear spontaneously with continuation of treatment.

The side effects that may be caused by Vitamina B6 are as follows:

- long-term use of high doses of Vitamina B6 is associated with serious peripheral neuropathy;
- insecure walking;
- drowsiness;
- numbness of the feet;
- paraesthesia;
- low levels of uric acid;
- ataxia and photoallergic reaction.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE VITAMINA B6

Keep out of the reach and sight of children!

Do not use Vitamina B6 after the expiry date which is stated on the package.

Do not store above 25°C.

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Vitamina B6 25 mg tablets contain

The active substance is pyridoxine hydrochloride (vitamin B6).

Each tablet contains 25 mg pyridoxine hydrochloride.

The excipients are: lactose, microcrystalline cellulose, talc and magnesium stearate.

What Vitamina B6 100 mg / 2 ml solution for injection contains

Each ampoule 2 ml contains 100 mg pyridoxine hydrochloride.

The excipients are: hydrochloric acid (may be added for pH adjustment), water for injection.

Content of the pack:

Tablets: carton with 30 tablets and carton with 60 tablets.

Solution for injection: carton box with 10 ampoules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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