

VITAMINE 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.

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1. WHAT VITAMINE B6 IS AND WHAT IT IS USED FOR

Vitamine B6 (pyridoxine hydrochloride) is a water soluble vitamin. Actually, vitamin B6 means three similar components: pyridoxine, pyridoxal and pyridoxamine, from which is mainly used the pyridoxine in the form of hydrochloride. 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.

Vitamin 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 VITAMINE B6

Do not take Vitamine 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 Vitamine B6 administration in patients with cardiac pathology should be avoided.

Take special care with Vitamine B6

Ask your doctor before taking Vitamine 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

Vitamine B6 concomitantly.

This limit 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 Vitamine 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 Vitamine 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).

Vitamine 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 the advice of the pharmacist or doctor before taking this drug!

Breast - feeding

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

Vitamine 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 Vitamine B6

Vitamine 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 VITAMINE B6

Always take Vitamine 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 Vitamine 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 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 Vitamine B6

If you take more Vitamine 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 Vitamine 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Vitamine 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 Vitamine B6 are as follows:

- long – term use of high doses of Vitamine B6 is associated with serious peripheral neuropathy;
- insecure walking;
- drowsiness;
- numbness of the feet;
- paraesthesia;
- low levels of uric acid;
- alaxia 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 VITAMINE B6

Keep out of the reach and sight of children!

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

Store below 25°C.

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Vitamine B6 – Tablets 25 mg contain

The active substance is pyridoxine hydrochloride (vitamin B6).

Each tablet contains 25 mg pyridoxine hydrochloride.

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

What Vitamine B6 – Solution for injection 100 mg / 2 ml contains

Each ampoule 2 ml contains 100 mg pyridoxine hydrochloride.

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

Content of the pack:

Tablets: carton box with 10 tablets, carton box with 60 tablets.

Solution for injection: carton box with 10 ampoules.

Explanatory of the illustration icons on the packaging:



Prescription only medicine.



Without medical prescription.



Content.



Warning.



Solution for injection.



Tablet shape.

Marketing Authorisation Holder (MAH) and Manufacturer:



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Rruga "Myslym Keta"
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Tirana – ALBANIA

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