

PACKAGE LEAFLET: Information for the user

VITAMINA B12

Solution for injection – 100 mcg / 1 ml

Solution for injection – 500 mcg / 1 ml

(Cyanocobalamin)

Read this leaflet carefully before you start using 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 B12 is and what it is used for
2. Before you use Vitamina B12
3. How to use Vitamina B12
4. Possible side effects
5. How to store Vitamina B12
6. Other information

1. WHAT VITAMINA B12 IS AND WHAT IT IS USED FOR

Vitamin B12 (cyanocobalamin) takes part in all the metabolic processes of the organism and plays an important role especially in the synthesis of nucleoproteins. It is necessary for the development, normal haemopoiesis, the formation of the epithelial cells and for the maintenance of the normal function of the neuronal myelinic membranes. Cyanocobalamin is converted in two coenzymes: methylcobalamine (the conversion of homocysteine in methyonine) and deoxyadenosilcobalamine (the conversion of methylmalonylcoenzyme A in succinylcoenzyme A). These active coenzymes are essential for the development and replication of the cells of the

organism. Cobalamin forms a prosthetic group of the methionine-synthesis and acts as a carrier of the methyl group. The failure of this biochemical reaction because of the deficiency of cobalamin causes the development of megaloblastic anemia and neuropathy.

Vitamin B12 is rapidly absorbed from the injection site. The maximal levels in the serum are achieved within 1 hour after use. Vitamin B12 is bound to serum proteins. It is accumulated in the liver, from where it is slowly released. Within 48 hours after the injection of 100 to 1000 mcg, about 50 % to 98 % of these doses appear in the urine. Most of them are excreted within the first 8 hours.

Vitamin B12 solution for injection is indicated in the treatment and prophylaxis of the hematological and neurological disorders because of the deficiency of vitamin B₁₂ such as: reduction of the absorption of vitamin B12, eg. in pernicious anemia, total or subtotal gastrectomy, Crohn disease and idiopathic steatorrhea, disorders of the intestinal flora accompanied with tropical sprue (diarrhea), multiple diverticula of the small intestine, infestation with the parasite *Diphyllobotrium latum*, methylmalonic aciduria and in strict vegetarians and children fed from vegetarian mothers.

2. BEFORE YOU USE VITAMINA B12

Do not take Vitamina B12 if you:

- have a known hypersensitivity to cyanocobalamin or cobalt;
- are allergic to any of the excipients mentioned at the end of this leaflet;
- are being treated for toxic amblyopia or Leber's disease, as these optic neuropathies may degenerate further.

Take special care with Vitamina B12

In pernicious anemias, suitable dosages should be used; in this case the blood count should be regularly analysed, at least once every 3 months. If megaloblastic anemia does not react to the treatment, then the patient should be examined for the metabolism of folic acid.

Cyanocobalamin, if possible, should not be administered to patients suspected of vitamin B12 deficiency without having first confirmed the diagnosis. The use of daily doses greater than 10 micrograms may cause hematological response in patients with folate deficiency; indiscriminate use may mask the precise diagnosis. Conversely, folates may mask vitamin B12 deficiency. At

the beginning of the treatment, cardiac arrhythmias are reported as a result of hypokalaemia, which dictates the need to define and to carefully follow the potassium plasmatic level during this period.

During the use of Vitamina B12, urine may take a red colour.

Vitamin B12 (cyanocobalamin) should not be used for the treatment of megaloblastic anemia in pregnant women.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Vitamina B12. 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 B12 if you have been given any other drug during treatment, especially the following:

- chloramphenicol, which reduces the hematological effects of vitamin B12 in patients with pernicious anemia;
- colchicin, large amounts of alcohol, neomycin and para-aminosalicylic acid, which reduce the gastrointestinal absorption of vitamin B12.

Taking Vitamina B12 with food and drinks

There are no important data to mention.

Pregnancy

Ask your doctor or pharmacist if you are pregnant or if you are planning to become pregnant.

Vitamina B₁₂ (cyanocobalamin) should not be used for the treatment of megaloblastic anemia in pregnant women.

Breastfeeding

Ask your doctor or pharmacist if you are breastfeeding.

Driving and using machines

There are no important data to be mentioned.

3. HOW TO USE VITAMINA B12

Always use Vitamina B₁₂ 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 B₁₂ are too strong or too weak, talk to your doctor or pharmacist.

The dosage of the solution for injection is as follows, where doses are suitable both for *adults* as well as for *children*.

In pernicious anemia and in other macrocytic anemias, without neurological complications

Initially 250 mcg up to 1000 mcg, that are injected into the muscle, on alternate days, for 1 to 2 weeks and then is continued with 250 mcg weekly until the blood count is normalised. The maintenance dose is 1000 mcg monthly.

In pernicious anemia and other macrocytic anemias, with neurological complications

Initially 1000 mcg that are injected into the muscle, on alternate days as long as improvement occurs. The maintenance dose is 1000 mcg monthly.

In the prophylaxis of macrocytic anemia, accompanied with vitamin B12 deficiency, as a result of gastrectomia, some malabsorption syndromes and strong vegetarianism

250 mcg to 1000 mcg monthly.

If you take more Vitamina B12

If you take more Vitamina B₁₂ 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 B12

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 B12 may cause side effects, although not everybody manifests them. Ask your doctor for the following side effects that may appear to you.

Hypersensitivity to cyanocobalamin is rare, but in some cases exanthema with itching, tremor, chills, redness of the face and neck, nausea and dizziness and in extraordinary situations, anaphylactic shock may appear. In rare cases, acneiform and bullous manifestations are observed.

During the use of Vitamina B12, urine may take a red colour.

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 B12

Keep out of the reach and sight of children.

Do not use Vitamina B12 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 Vitamina B12 contains

The active substance is cyanocobalamin.

Each ampoule of 1 ml contains 100 mcg or 500 mcg cyanocobalamin.

The excipients are: sodium chloride, hydrochloric acid, water for injection.

Content of the pack

Carton box with 10 ampoules of 1 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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