

PACKAGE LEAFLET: Information for the patient

NEURO B

Solution for injection – (100 mg + 50 mg + 0.5 mg) / 2 ml

(Vitamin B1 + Vitamin B6 + Vitamin B12)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further question, ask your doctor or pharmacist.
- This medication has been prescribed for you. Do not pass it on to others. It may harm them, even if they may have the same symptoms as yours.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Neuro B is and what it is used for?
2. What you need to know before you take Neuro B
3. How to take Neuro B?
4. Possible side effects
5. How to store Neuro B?
6. Other information

1. WHAT NEURO B IS AND WHAT IT IS USED FOR

Neuro B contains the active substances Vitamin B1 (thiamine hydrochloride), Vitamin B6 (pyridoxine hydrochloride) and Vitamin B12 (cyanocobalamin) which are part of vitamin B group.

These vitamins enter into the composition of the enzymes, which catalyze reactions during metabolism of sugars, lipids and proteins. The combination of B group vitamins is used to influence in a variety of important processes and functions of the organism and mainly for the influence on inflammatory and degenerative diseases of the nerves and motor nerves.

Neuro B, as a solution for injection, is used in the complex treatment of the following diseases and states:

- treatment of vitamin B deficiency, in dermatitis, eczema, psoriasis, exudative diathesis, acne;
- inflammatory and degenerative processes of peripheral nerves - neuritis, polyneuritis (alcoholic, post infective and toxic, in case of diabetes), neuralgia, myalgia, paresthesia;
- during treatment with some medicines such as isoniazid, cycloserine;
- treatment of macrocytic anemia;
- might be of benefit as an adjunct in the management of alcohol withdrawal;
- after gastrectomy or extensive ileal resection;
- it may positively affect on stabilizing premenstrual syndrome.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NEURO B

Do not take Neuro B if you:

- are hypersensitive (allergic) to any of the active substances or to any of the other ingredients of Neuro B, since anaphylactic reactions may occur;
- are pregnant;
- suffer from polycythemia vera;
- suffer from malignant processes;
- suffer from acute thromboembolism (blocking of a blood vessel by thrombus formation);
- suffer from erythrosis and erythremia (blood disease with increased number of red blood cells).
- are with Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

Take special care with Neuro B

Neuro B should be used with caution by patients with severe or acute forms of decompensated heart failure and stenocardia.

Long-term use of high doses of pyridoxine is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial.

Cyanocobalamin should, if possible, not be given to patients with suspected vitamin B12 deficiency without first confirming the diagnosis. Regular monitoring of the blood is advisable.

Use of daily doses greater than 10 micrograms may produce a hematological response in patients with folate deficiency; indiscriminate use may mask the right diagnosis. Conversely, folates may mask vitamin B12 deficiency.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Drugs that can interact with Neuro B are:

neuromuscular blocking agents: vitamin B₁ may enhance the effect of neuromuscular blocking agents;

levodopa: vitamin B6 reduces the effects of levodopa, but this does not occur if a dopa decarboxylase inhibitor is also given;

phenobarbital: vitamin B6 has been reported to decrease serum concentrations of phenobarbital; hydralazine, isoniazid, penicillamine, and oral contraceptives may increase the requirements for vitamin B6;

chloramphenicol: parenteral chloramphenicol may attenuate the effect of vitamin B12 in anaemia.

Taking Neuro B with food and drinks

There are no data on the need for a special diet or food and drinks restriction at the time of treatment with this medicinal product.

Pregnancy and breastfeeding

Pregnancy

Tell your doctor or pharmacist if you are pregnant, think you may be pregnant or are planning to get pregnant.

Vitamin B6 and B12 diffuse across the placenta, therefore Neuro B is not recommended to be used during pregnancy.

Breastfeeding

Tell your doctor or pharmacist if you are breastfeeding.

Severely thiamine-deficient mothers should avoid breast-feeding as toxic methyl-glyoxal is present in milk. It is not recommended to be used during breastfeeding, only if it is necessary.

Driving and using machines

No studies have been performed on the effect of this drug on the ability to drive and use machines.

3. HOW TO TAKE NEURO B

Always take Neuro B according to your doctor advice. Check with your doctor or pharmacist if you are not sure.

The usual doses are described below:

In adults, intramuscularly injected 2 ml 1-2 times per day. The duration of treatment is done under medical evaluation.

In children, the dosage is adjusted based on their age and their illness.

If you take more Neuro B than you should

If you take more Neuro B than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or emergency call to get an opinion on the risk and advice on the actions that should be taken.

Do not take more Neuro B than the amount that your doctor recommends.

In rare cases fatal anaphylactic shock may occur.

Vitamin B6 is usually nontoxic, however, chronic administration of high doses has been associated with adverse neurologic effects.

Vitamin B12 is usually nontoxic even in high dosage, however mild transient diarrhea, peripheral vascular thrombosis, itching transitory exanthema, urticaria, feeling of swelling of the entire body, anaphylaxis, and death have been reported in patients receiving parenteral vitamin B12.

Treatment

Isoniazid is a Vitamin B6 antidote.

If you forget to take Neuro B

Do not take a double dose to make up for a forgotten dose.

If you forget to take Neuro B, take your dose as soon as you remember unless it is time to take the next dose. Use doses at the right time.

4. POSSIBLE SIDE EFFECTS

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

Neuro B does not give any adverse effects in the recommended doses.

In rare cases: sweating, itching, and urticaria can be noticed.

Adverse effects with thiamine are rare, but hypersensitivity reactions have occurred, up to fatal anaphylactic shock.

Tenderness and induration, burning or stinging at the injection site may occur following intramuscular injection of Neuro B.

Long-term use of high doses of vitamin B₆ is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial.

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

5. HOW TO STORE NEURO B

Keep this medicine out of the sight and reach of children.

Do not use Neuro B after the expiry date which is stated on the packaging.

Store at 2°C – 8°C!

Do not freeze.

Keep Neuro B away from the light!

6. OTHER INFORMATION

What Neuro B solution for injection contains

The active substances are: vitamin B1 (thiamine hydrochloride), vitamin B6 (pyridoxine hydrochloride) and vitamin B12 (cyanocobalamin).

Each ampoule 2 ml contains 100 mg vitamin B1, 50 mg vitamin B6 and 0.5 mg vitamin B12.

The excipients are: methyl hydroxybenzoate, sodium metabisulphite, sodium dihydrogenphosphate dihydrate, disodium hydrogenphosphate dihydrate, sodium hydroxide, and water for injection.

Contents of the pack

Carton box with 10 ampoules of 2 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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