Martin Dow

Neurobion® Injection
(Vitamin B_1 + B_6 + B_{12})

نیوروبیان® انجکشن
(وٹامن بی۱+بی۶+بی۱۲)

Composition:
Neurobion® Injection: **Each 3 ml contains:**
Vitamin B1 (Thiamine Hydrochloride), USP.....100 mg
Vitamin B6 (Pyridoxine Hydrochloride), USP .... 100 mg
Vitamin B12 (Cyanocobalamin), USP..... 1000 mcg

DESCRIPTION
Neurobion Injection & Tablet is a combination of Vitamin B1, B2 & B6.

THERAPEUTIC INDICATIONS
Treatment of neuritis and neuralgia (neuropathies) such as:
- Trigeminal neuralgia
- Intercostal neuralgia
- Ischialgia
- Lumbar syndrome
- Cervical syndrome
- Shoulder-arm syndrome
- Radiculoneuritis due to degenerative diseases of the vertebral column
- Facial paresis

Herpes zoster.

DOSAGE AND ADMINISTRATION
Neurobion Injection
In severe cases 1 ampoule daily by deep intramuscular via slow intragluteal, injection. This dosage is to be continued until the disappearance of the acute symptoms. In milder cases and for follow-up treatment 1 ampoule 2-3 times weekly.
Because of the possibility of sensitization against vitamin B1, intravenous injection of Neurobion should be made cautiously and slowly while observing the patient for possible allergic reaction. Combination with glucose solution is often beneficial in intravenous injection.

Paediatric population:
Neurobion solution for injection should not be administered to children under 14 years old.

CONTRAINDICATIONS
- Hypersensitivity to any of the active ingredients or excipients of the product.
- The use of the medicinal product is not recommended in case of severe cardiac conduction disorders and acute decompensated cardiac failure. Must not be used during pregnancy and breast-feeding.

Applies only to solution for injection containing benzyl alcohol: Treatment of children below the age of 3 years due to the risk of fatal toxic reactions arising from exposure to benzyl alcohol more than 90 mg/ kg/ day.

WARNINGS AND PRECAUTIONS
- The clinical picture as well as the laboratory parameters of funicular myelosis or of pernicious anaemia can lose specificity by administration of vitamin B12.
- If symptoms of peripheral sensory neuropathy (paraesthesia) occur, the dosage should be reviewed and treatment with the medicinal product discontinued, if necessary. Neuropathies have been observed under long-term intake (over 6-12 months) of daily dosages exceeding 50 mg vitamin B6 as well as in short-term intake (over 2 months) of more than 1 g vitamin B6 per day. Therefore, regular monitoring is recommended under long-term treatment.
- Solution for injection should be injected only intramuscularly (I.M.), not intravenously (I.V.), to avoid cardiovascular adverse effects. In case of inadvertent intravenous injection, the patient's heart activity should be monitored (ECG) or the patient should be hospitalised depending on the severity of cardiovascular symptoms (arrhythmias, bradycardia).
- Occupational exposure to thiamine has produced contact dermatitis. These sensitized individu als may experience a relapse of dermatitis after subsequent exposure.
- This medicinal product should not be given to patients with suspected vitamin B12 deficiency without first confirming the diagnosis. Regular monitoring of the blood is advisable.
- This medicinal product should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

Applies only to medicinal products containing lactose and sucrose as excipients: Neurobion contains lactose and sucrose; therefore, its use is not recommended in patients with rare hereditary galactose or fructose intolerance, glucose-galactose malabsorption, Lapp lactase deficiency, or sucrose-isomaltose insufficiency.

ADVERSE EFFECTS
- **Not known:** Gastrointestinal complaints such as nausea, vomiting, diarrhoea, and abdominal pain, chromaturia ("reddish urine", appeared during the first 8 hours after an administration and typically resolves within 48 hours), dermatitis and severe peripheral neuropathies. Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may cause peripheral sensory neuropathy. Gastrointestinal complaints, such as nausea, vomiting, diarrhoea and abdominal pain, Allergic reactions, eczematous skin alterations and a benign form of acne have been observed after high-dose vitamin B12.
- **Very rare:** Hypersensitivity reactions, such as sweating, tachycardia, and skin reactions with itching and urticaria, anaphylactic shock, injection site reactions.

DRUG INTERACTIONS
- The effect of L-dopa may be reduced when vitamin B6 is administered concomitantly.
- Thiamine is inactivated by 5-fluorouracil as the latter competitively inhibits the phosphoryla tion of thiamine-to-thiamine pyrophosphate.
- Antacids diminish the absorption of thiamine.
- Loop diuretics, e.g., furosemide that inhibit tubular reabsorption may cause increased excretion of thiamine in long-term therapy and, thus, lowering of the thiamine serum level.
- The simultaneous administration of pyridoxine antagonists (e.g., isoniazide (INH), hydralazine, D-penicillamine or cycloserine) may decrease the efficacy of vitamin B6 (pyridoxine).
- Long term use of acid-lowering agents may lead to vitamin B12 deficiency.
- Alcohol and black tea diminish the absorption of thiamine.
- Product reduces the activity of altretamine.
- Product may decrease serum concentrations of phenobarbital and phenytoin.
- Oral contraceptives- Serum concentration of vitamin B6, vitamin B12 may be decreased by use of oral contraceptives.
- Neomycin, amino salicylic acid, histamine H2-antagonists, omeprazole, colchicine - Absorption of the product from the gastrointestinal tract may be reduced by neomycin, amino salicylic acid, histamine H2-antagonists, omeprazole, and colchicine. No interaction is likely when product is given by injection.
- Parenteral chloramphenicol may attenuate the effect of this medicinal product in anaemia.

PREGNANCY AND LACTATION

Pregnancy: No risks have become known associated with the use of Neurobion during pregnancy at the recommended dosage. The treating physician should decide about the use of this product during pregnancy after carefully weighing the risk-to-benefit ratio.

Lactation: Vitamins B1, B6 and B12 are secreted into human breast milk, but risks of overdose for the infant are not known. In individual cases, high doses of vitamin B6, i.e., > 600 mg daily, may inhibit the production of breast milk. The treating physician should decide about the use of this product during pregnancy after carefully weighing the risk-to-benefit ratio.

CLINICAL PHARMACOLOGY

Vitamin B1 (Thiamine): Thiamine or thiamin, also known as vitamin B1 and aneurine hydrochloride. It decomposes if heated. Its chemical structure contains a pyrimidine ring and a thiazole ring. Thiamine plays an important role in helping the body metabolize carbohydrates and fat to produce energy. It is essential for normal growth and development and helps to maintain proper functioning of the heart and the nervous and digestive systems. Thiamine is water-soluble and cannot be stored in the body; however, once absorbed, the vitamin is concentrated in muscle tissue.

Vitamin B6 (Pyridoxine Hydrochloride): Vitamin B6 is a water-soluble vitamin. Pyridoxal phosphate (PLP) is the active form and is a cofactor in many reactions of amino acid metabolism, including transamination, deamination, and decarboxylation. PLP also is necessary for the enzymatic reaction governing the release of glucose from glycogen.

Vitamin B12 (Cyanocobalamin): Cyanocobalamin is a compound that is metabolized to a vitamin in the B complex commonly known as vitamin B12 (or B12 for short). Vitamin B12 is important for the normal functioning of the brain and nervous system and for the formation of blood. It is involved in the metabolism of every cell of the body, especially affecting the DNA synthesis and regulation but also fatty acid synthesis and energy production. Its effects are still not completely known.

Combinations of vitamins B1, B6 and B12: Vitamins B1, B6 and B12 have, singly but also together as a result of biochemical links, a special significance for the metabolism of the nervous system, which justifies their combined use. Animal studies have shown that this combination of B-complex vitamins accelerates regenerative processes in damaged nerve fibers, which finally leads to enhanced restoration of function and muscle innervation. In the model of experimental diabetes in rats, administration of B-complex vitamins prevented or attenuated the characteristic nerve damage, so that deterioration of the functional properties was counteracted.

In several pain models in rats, vitamins B1, B6 and B12 have demonstrated an antinociceptive effect, the efficacy of the combination exceeding that of the individual vitamins. Moreover, electrophysiological experiments have revealed that direct influences of the vitamins on nociceptive processing paths in the spinal cord or in the thalamus might be the mechanisms responsible for clinically observed analgesia. Dosages of B-complex vitamins not able to produce antinociceptive effects anymore can clearly potentiate the effect of analgesics/NSAIDs (e.g. paracetamol, diclofenac).
These pharmacological properties of the mixture of vitamins B1, B6 and B12 find their equivalent in the results obtained in clinical double-blind trials, which have proved the efficacy of B-complex vitamins in diseases of the nervous system.

OVERDOSAGE

Vitamin B1: In individual cases, the parenteral injection of large doses of thiamine has led to anaphylactic shocks. Thiamine has a broad therapeutic range. Very high doses (over 10 g) have a ganglion-blocking effect, similar to that of curare, and suppress the conduction of nerve impulses.

Vitamin B6: Prolonged overdose of vitamin B6, i.e. for longer than 2 months and more than 1 g per day, may lead to Neurotoxic effects. The toxic potential of vitamin B6 can be considered as very low. Long-term intake (> 6-12 months) of a daily dosage > 50 mg vitamin B6 may, however, cause peripheral sensory neuropathy and other sensorial neuropathy syndromes. These symptoms improve gradually upon vitamin discontinuation. Neuropathies with ataxia and sensitivity disorders, cerebral convulsions with EEG changes as well as, in individual cases, hypochromic anaemia and seborrheic dermatitis have been described after administration of more than 2 g daily.

Vitamin B12: Allergic reactions, eczematous skin changes and a benign form of acne have been observed after high parenteral doses (in rare cases also after oral doses). Intramuscular and subcutaneous doses as large as 1000 mcg and intravenous doses as high as 3000 mcg have been administered without side effects.

Presentation

Neurobion® Injection: Available pack of 25 x 3 ml ampoules

Storage
Store below 30 °C.
Protect from light and heat.
Keep all medicines out of the reach of children.

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور گرمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

Innovator's Specs.

Manufactured by:
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