Neurobion® solution for injection

Composition
Each ampoule contains, as active ingredients, 100 mg vitamin B1 (thiamine hydrochloride), 100 mg vitamin B6 (pyridoxine hydrochloride), 1000 microgram vitamin B12 (cyanocobalamin) in 3 ml of aqueous solution for injection.

Excipients: potassium cyanide, sodium hydroxide solution, water for injection

Properties
Neurobion is a combination of three essential neurotropic vitamins (B1, B6 and B12) in high dosage. Vitamins B1, B6 and B12 are of special importance for the metabolism in the peripheral and central nervous system. Their effect on the regeneration of nerves has been shown in various investigations using the vitamins individually and in combination.

Indication
Neurological systemic diseases due to a severe lack in vitamin B1, B6 and B12, when oral therapy is insufficient.

Contraindications
Neurobion must not be used in patients hypersensitive to any of the active ingredients or excipients of the product (see ‘Composition’).

Warnings and precautions
In the literature neuropathies are described under long term intake (6-12 months) of more than 50 mg mean daily dose of vitamin B6. Therefore, under long-term treatment regular monitoring is recommended.

Pregnancy and lactation
No risks have become known associated with the use of Neurobion during pregnancy at the recommended dosage.

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.

Adverse effects
Hypersensitivity reactions to vitamin B1 or B12, such as sweating, tachycardia (rapid heart beat), and skin reactions with itching and urticaria may occur.

In single cases, conditions of shock have been observed after treatment with vitamin B1 or B12 injections.

Gastrointestinal complaints, such as nausea, vomiting, diarrhoea or abdominal pain may occur.

Individual cases of acne have been reported after high parenteral dose of vitamin B12.

Injection site reactions may occur.

Please speak to your doctor, if such symptoms or other unwanted effects occur.

Interactions
L-dopa: The effect of L-dopa may be reduced when vitamin B6 is administered concomitantly.

Pyridoxine-antagonists, e.g. isoniazid (INH), cycloserin, penicillamin, hydralazine:
the efficacy of vitamin B6 (pyridoxine) may be decreased.

Loop diuretics, e.g. furosemide: In long-term use, the blood level of thiamine may be reduced.

Dosage and administration
Neurobion is administered by intramuscular injection.

In severe cases 1 ampoule daily is given until the acute symptoms subside. For follow-up therapy 2-3 ampoules are given per week. In milder conditions this dosage is sufficient from the beginning.

The duration of the treatment is determined by the doctor.

Overdose
Prolonged overdose of vitamin B6, i.e. for longer than 2 months and more than 1 g per day, may lead to neurotoxic effects.

Storage and stability
Store between 2 to 8 degrees

Do not use after the expiry date.

Keep medicines out of the reach of children.

Presentations
3, 6, and 15 ampoules of 3 ml.

Not all containers or pack sizes may be registered or marketed.

Date of information
April 2011

Manufacturer:
Merck KGaA, Darmstadt, Germany

Marketing Authorization Holder:
Merck KGaA & Co., Spittal, Austria

THIS IS A MEDICAMENT
Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.