



Composition

Each NEUROBION® 5000 ampoule I contains:
Vitamin B1 (Thiamine Hydrochloride) 100 mg
Vitamin B6 (Pyridoxol Hydrochloride) 100 mg
Each NEUROBION® 5000 ampoule II contains:
Cyanocobalamin 5000 mcg

Pharmacological Class

Alimentary tract and metabolism, vitamin B1 in combination with vitamin B6 and vitamin B12.
ATC Code : A11DB

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.

Thiamine functions in carbohydrate metabolism, in human body is converted to Thiamine Pirophosphate (active form) as a coenzyme in the decarboxylation of α - keto acids.

In human body Pyridoxine HCl will be transferred to pyridoxine phosphate, co-enzyme reaction in carboxylation and transamination, which are involved in protein and amino acids metabolism.

Vitamin B12 is essential in nucleic acid and myelin synthesis, for cell growth and replication and maintaining the integrity of nervous tissue.

Indication

Treatment of vitamin B1, B6 and B12 deficiency in case of beri-beri, peripheral neuritis and neuralgia.

Contraindication

- NEUROBION® must not be used in patients hypersensitive to any of the active ingredients or excipients of the product (see 'Composition').
- Children below the age of 18 years

Warning 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.

This medication is used to treat a lack of vitamins (deficiency) when the form taken by mouth can not be used or would not work as well as the injection.

Do not share this medication with others. This product is not a substitute for a proper diet. Remember that it is best get your vitamins from healthy foods.

Safe injection practices:

Do not re-use syringes and needles. Syringes and needles must be disposed immediately after use. Used syringes and needles must not be disposed in waste bins or toilets, but they must be disposed in a special sharps container

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

As most undesirable effects are based on post-marketing spontaneous reporting, precise frequency estimation is not possible. The following definitions apply to frequency terminology used hereafter:

Very common $\geq 1/10$
Common $\geq 1/100, < 1/10$
Uncommon $\geq 1/1,000, < 1/100$
Rare $\geq 1/10,000, < 1/1,000$
Very rare $\geq 1/10,000$ including individual cases
Frequency not known can not be estimated from the available data

Immune system disorder:

Frequency not known: Hypersensitivity reactions to B1, B6 and B12 such as sweating, tachycardia (rapid heart beat), and skin reactions with itching and urticaria may occur
Anaphylactic shock

Very rare:

Gastrointestinal disorder:

Frequency not known: Gastrointestinal complaints, such as nausea, vomiting, diarrhoea and abdominal pain

Skin and subcutaneous tissue disorder:

Frequency not known: Isolated cases of acne or eczema have been reported after high parenteral doses of vitamin B12.

General disorder and administration site conditions:

Frequency not known: Injection site reaction

Renal and urinary disorders:

Frequency not known: Chromaturia ("reddish urine", appeared during the first 8 hours after an administration and typically resolves within 48 hours)

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.

Long term use of acid-lowering agents may lead to vitamin B12 deficiency.

Effects on ability to drive and use machines

No effects of the product on the ability to drive or use machine are known

Dosage and Administration

Neurobion is administered by intramuscular injection.

For initial treatment of severe cases 1 pair ampoule daily is given until the acute symptoms subside. For follow up therapy 2-3 pairs ampoules are given per week. For less severe cases, NEUROBION® 5000 injectable with a lower dose of vitamin B12 is available. 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. Sensorial neuropathy and other sensorial neuropathy syndromes which can be caused by long-term administration of high doses of pyridoxine improve gradually upon vitamin discontinuation.

Incompatibility

- It is not recommended to use NEUROBION® injection solution together with other medicinal products in a "mixed injection" or infusion
- Vitamin B1 is completely degraded sulfite-containing infusion solutions
- Other vitamins, especially cyanocobalamin, may be inactivated in the presence vitamin B1 degradation products

Presentation

Box of 20 pairs ampoule @ 1 ml

"On medical prescription only"

Store at temperature below below 30°C

Manufactured by

PT. Meprofarm
Bandung, Indonesia
for
PT. Darya-Varia Laboratoria Tbk
Gunung Putri, Bogor, Indonesia

Reg. No. : XXX-XXXXXXX

"HARUS DENGAN RESEP DOKTER"

1047050292V03

APPROVED

By Rini Mardikawati (6 Jul 2020, 11:35 pm)

APPROVED

By Wens Arpandy (3 Jul 2020, 10:56 am)

SPECIFICATION

Material name	: Neurobion 5000 Ampul Insert	Packing condition, if applicable:	
Article No	: 10470505292V03	Length of alufol	: -
Dimension	: 134 x 205 mm	Pcs per roll / sheet	: -
Material Quality	: HVS 60 gsm	Pcs perbundle	: 25 pcs
Varnish & Finishing	: -	Pcs pershipper	: -
Barcode No.	: -	Other condition	: Terlipat
Pharmacode No.	: -	(eg. Folded leaflet)	: Lipat 2, Lipat 2, Lipat 2 tengah
Color	: ■ Biru(P662C)	Revision History	: Old no 10470505292V02
Color code	: ■ Biru(P662C)	- Update CCDS	
	5 x 4 mm, 12 mm dari tepi kiri		
		Prepared by	: ferry

REFERENCE DATE :

File name: Neurobion 5000 Ampul Insert (10470505292V03)