



NEUROBION® Ampoules

Active ingredients: Thiamine hydrochloride (vitamin B₁), Pyridoxine hydrochloride (vitamin B₆), Cyanocobalamin (vitamin B₁₂)

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have 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 symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What NEUROBION® ampoules are and what they are used for

NEUROBION® ampoules contain a combination of vitamins B₁, B₆ and B₁₂ which are of particular importance for the normal functioning of the neural metabolism. Like all other vitamins, they are essential nutrients which the body cannot produce itself.

There are indications that vitamin B₁ exerts a blocking effect on pain conduction (antinociceptive effect).

In which conditions are **NEUROBION®** ampoules indicated? Neurological systemic diseases due to a severe lack in vitamin B₁, B₆ and B₁₂ when oral therapy is insufficient.

2. Before you use NEUROBION® ampoules

Do not use NEUROBION® ampoules

- if you are allergic to vitamins B₁, B₆ and B₁₂ or any of the other ingredients of this medicine listed in section 6.
- **NEUROBION®** ampoules must not be used for children and adolescents (< 18 years) due to its high active substance content.

Warnings and precautions

NEUROBION® ampoules must not be administered by intravenous injection.

Short-term injection of vitamin B₁₂ may temporarily impair the diagnosis of funicular myelosis (disease of the spinal cord) or pernicious anaemia (certain type of anaemia).

Prickling and tingling in hands and feet (signs of peripheral sensory neuropathy or paraesthesia) have been observed under long-term use (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. If you notice prickling or tingling, please consult your doctor who will review the dosage and discontinue treatment with the medicinal product, if necessary.

Other medicines and NEUROBION® ampoules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Vitamin B₁ loses its efficacy when administered concurrently with the anticancer agent (cytostatic) 5-fluorouracil.
- Long-term therapy with certain diuretics, e.g. furosemide may lead to vitamin B₁ deficiency due to increased excretion of vitamin B₁ in the urine.
- Vitamin B₆ can reduce the effect of L-dopa (agent to treat Parkinson's disease).
- The concurrent administration of pyridoxine antagonists (medicinal products that among others counteract the effects of vitamin B₆ such as isoniazide (INH), hydralazine, cycloserine, D-penicillamine) may reduce the effect of vitamin B₆.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are only insufficient animal studies on the effect of this medicinal product on pregnancy and the child's development. The possible risk for human beings is not known. The use of this product during pregnancy is not recommended.

Vitamins B₁, B₆ and B₁₂ are secreted into human breast milk. High doses of vitamin B₆ (600mg daily) can inhibit the production of breast milk. The use of this product during breast-feeding is not recommended. Therefore, the advantages of breast-feeding for the infant should be carefully weighed against the therapeutic benefit for the women in order to decide to either discontinue breast-feeding or therapy with **NEUROBION®** ampoules.

Driving and using machines

NEUROBION® ampoules have no or negligible influence on the ability to drive and use machines.

NEUROBION® ampoules contain sodium and potassium

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule. It is, thus, virtually, sodium-free.

This medicinal product contains less than 1 mmol potassium (39 mg) per ampoule. It is, thus, virtually, potassium-free.

3. How to use NEUROBION® ampoules

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is:

In severe (acute) cases: One ampoule daily until the acute symptoms have subsided.

Once the symptoms have improved: One ampoule 1-3 times per week.

To support or continue initial injection therapy and for the prevention of recurrence, intake of **NEUROBION®** coated tablets is recommended.

Mode of administration

For intramuscular injection.

NEUROBION® ampoules are to be injected into a muscle (e.g. gluteal muscle).

Use in children and adolescents

NEUROBION® ampoules must not be used in children and adolescents (< 18 years).

If you take more NEUROBION® ampoules than you should:

Vitamins B₁, B₆ and B₁₂ have a wide therapeutic range, i.e. the range between underdosing and overdosing is very large.

Vitamin B₁: The following complaints have been reported after administration of more than 100 times the recommended dose: Headache, spasms, weakness, paralysis, heart rhythm disturbances and allergic reactions.

Vitamin B₆: Long-term use (more than 6-12 months) of vitamin B₆ in daily doses exceeding 50 mg as well as short-term use (over 2 months) of daily doses exceeding 1 g can lead to nerve-damaging (neurotoxic) effects. Nerve lesions with movement disorders and sensory disturbances, spasms and, in individual cases, changes in the blood count as well as inflammatory skin reactions after intake of daily doses exceeding 2 g have been described. These complaints gradually improve after discontinuation of vitamin administration.

Vitamin B₁₂: Eczema and acne-like skin rash have been observed in rare cases after administration of high doses.

If you have further questions about the use of this medicinal product, contact your doctor or pharmacist.

4. Possible side effects

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

In the following, side effects are classified by organ system and frequency.

Very rare (may affect up to 1 of 10,000 treated persons)

- Hypersensitivity reactions, e.g. sweating, rapid heart beat and skin reactions such as itching and nettle rash. Severe allergic (hypersensitivity) reactions, often accompanied by drop in blood pressure, dizziness, nausea and possibly difficulty breathing (anaphylaxis).

Not known (frequency cannot be estimated from the available data):

- Long-term use (more than 6-12 months) of a daily dosage exceeding 50 mg vitamin B₆ may cause peripheral sensory neuropathy (nerve disease with prickling and tingling). The complaints gradually improve after discontinuation of vitamin administration.
- Gastrointestinal complaints such as nausea, vomiting, diarrhoea and abdominal complaints.
- Eczema and acneiform skin rash have been observed after high-dose parenteral use of vitamin B₁₂.
- Chromaturia (i.e. a reddish-brown discoloration of the urine occurred during the first few hours after intake with normalisation typically setting in after discontinuation of the product).
- Reactions at the injection site

5. How to store NEUROBION® ampoules

Store in a refrigerator (2°C–8°C).

Store in the original carton to protect from light.

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

Do not use this medicine after the expiry date which is stated on the folding box/container. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste, but dispose them in puncture-proof containers intended for this purpose. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What NEUROBION® ampoules contains

- The active substances are: Thiamine hydrochloride (vitamin B₁), pyridoxine hydrochloride (vitamin B₆) and cyanocobalamin (vitamin B₁₂)
- One ampoule of 3 ml contains:

Thiamine hydrochloride (vitamin B ₁)	100 mg
Pyridoxine hydrochloride (vitamin B ₆)	100 mg
Cyanocobalamin (vitamin B ₁₂)	1 mg
- Other ingredients: Sodium hydroxide (for pH adjustment), potassium cyanide, water for injection.

What NEUROBION® ampoules look like and contents of the pack

NEUROBION® ampoules contain a red, clear solution for injection in 3-ml amber-glass ampoules.

NEUROBION® ampoules are available in packs of 3, 6 and 15 ampoules of 3ml.

Not all pack sizes may be registered or marketed.

Manufacturer:

Cenexi HSC – France

Marketing Authorisation Holder:

P&G Health Germany GmbH, Germany

Last revision date: April 2018.

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 for you.
- 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