



NEUROBION® Coated tablets

Active substances: Thiamine disulphide (vitamin B₁), Pyridoxine hydrochloride (vitamin B₆), Cyanocobalamin (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 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® TABLETS IS AND WHAT IT IS USED FOR

NEUROBION® tablets contains 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.

The effect of B vitamins in diseases of the nervous system involves compensation of accompanying vitamin B deficiencies and stimulation of natural healing processes in the nervous tissue.

There are indications of an analgesic effect of vitamin B₁.

In which conditions are NEUROBION® tablets indicated?

For the supportive treatment of neuritis and non-inflammatory diseases of the nerves e.g.:

- pain and/or paralysis in the facial nerves (trigeminal neuralgia, facial paresis)
- ischialgia
- pain in the area of the intercostal nerves, cervical vertebral column, shoulders and arms, as well as of the lumbar vertebral column.
- states of irritation due to diseases of the vertebral column

2. BEFORE YOU TAKE NEUROBION® TABLETS

Do not take NEUROBION® tablets

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

Warnings and precautions

Talk to your doctor or pharmacist before taking **NEUROBION®** tablets.

Prickling and tingling of hands and feet (signs of peripheral sensory neuropathy or paraesthesia) have been observed under long-term intake of daily dosages exceeding 50 mg vitamin B₆ as well as in short-term intake of more than 1 g vitamin B₆ per day. If you notice prickling or tingling, please consult your doctor. Your doctor will review the dosage and discontinue treatment with the medicinal product, if necessary. Consequently, regular monitoring is recommended in long-term use.

Other medicines and NEUROBION® tablets

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 cytostatic agent (for cancer treatment) 5-fluorouracil.
- Antacids diminish the uptake of vitamin B₁₂.
- Long-term therapy with certain diuretics, e.g. furosemide may lead to vitamin B₁₂ deficiency due to increased excretion of vitamin B₁₂ 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.

NEUROBION® tablets with food, drink and alcohol

Alcohol and black tea reduce the uptake of vitamin B₁.

The concomitant consumption of beverages containing sulphite (e.g. wine) may cause degradation of vitamin B₁₂ resulting in loss of efficacy.

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 taking this medicine.

The daily vitamin requirements of pregnant women and nursing mothers is to be ensured through balanced nutrition. This medicinal product is (due to the amounts of active substances contained) only indicated for the treatment of vitamin deficiency and may, therefore, be taken only after a doctor has carefully weighed the risks and benefits.

Vitamins B₁, B₆ and B₁₂ are secreted into human breast milk. High doses of vitamin B₆ can inhibit the production of breast milk.

The doctor decides in each individual case whether **NEUROBION®** tablets may be taken during pregnancy or the nursing period.

Driving and using machines

NEUROBION® tablets has no or negligible influence on the ability to drive and use machines.

NEUROBION® tablets contains sucrose

This medicine contains sucrose. Please take **NEUROBION®** tablets only after having consulted your doctor if you know that you suffer from sugar intolerance.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, i.e. it is virtually "sodium-free".

3. HOW TO TAKE NEUROBION® TABLETS

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

The recommended dose is 1 to 3 tablets daily, depending on the doctor instructions.

Method of use

For oral intake.

The coated tablets are to be taken whole with plenty of liquid after meals.

Use in children and adolescents

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

If you take more NEUROBION® tablets than you should

Vitamin B₁: No cases of overdose have been reported to date after intake of vitamin B₁.

Vitamin B₆: Long-term intake (more than 6-12 months) of vitamin B₆ in daily doses exceeding 50 mg as well as short-term intake (over 2 months) of daily doses exceeding 1 g can have 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 have been described with intake of daily doses exceeding 2 g. These complaints gradually improve after discontinuation of vitamin intake.

Vitamin B₁₂: Allergic reactions, eczema and acneiform skin rash have been observed in rare cases.

If you forget to take NEUROBION® tablets

Do not take a double dose to make up for a forgotten dose. Simply take the next dose at the usual time.

If you have further questions about the intake of this medicine, please ask your doctor or your pharmacist.

4. POSSIBLE SIDE EFFECTS

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

In the following, the undesirable effects are classified by 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.

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 intake.
- Gastrointestinal complaints such as nausea, vomiting, diarrhoea and abdominal complaints.
- 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).

5. HOW TO STORE NEUROBION® TABLETS

Do not store above 25°C.

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 blister/container. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What **NEUROBION®** tablets contains

- The active substances are: Vitamin B₁ + vitamin B₆ + vitamin B₁₂

One coated tablet contains:

Thiamine disulphide (vitamin B ₁)	100 mg
Pyridoxine hydrochloride (vitamin B ₆)	200 mg
Cyanocobalamin (vitamin B ₁₂)	200 µg

– other ingredients:

Magnesium stearate, methyl cellulose, sodium starch glycolate, gelatin, mannitol, talc, glycerol, colloidal anhydrous silica, purified water, montan-glycol wax, acacia, povidone, calcium carbonate, kaolin, titanium dioxide (E 171), sucrose.

What NEUROBION® tablets looks like and contents of the pack

NEUROBION® tablets are white, shiny, round, biconvex coated tablets.

NEUROBION® tablets are available in packs of 20 tablets (2 strips), packs of 30 tablets (3 strips) and glass bottles of 100 tablets.

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

Marketing Authorisation Holder:

P&G Health Germany GmbH, Germany

Manufacturer:

P&G Health Austria GmbH & Co. OG, Austria

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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