

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Neuromultivit film-coated tablets

2. Qualitative and quantitative composition

1 Neuromultivit film-coated tablet contains

Thiamine hydrochloride (Vitamin B ₁).....	100 mg
Pyridoxine hydrochloride (Vitamin B ₆).....	200 mg
Cyanocobalamin (Vitamin B ₁₂).....	0.2 mg

For excipients, see 6.1.

3. Pharmaceutical form

Film-coated tablets

4. Clinical particulars

4.1. Therapeutic indications

For supporting the treatment of neuropathies, such as:

- polyneuropathies of various etiology
- neuritis and neuralgia
- radiculitis as a result of degenerative spinal column diseases
- intercostal neuralgia
- trigeminal neuralgia
- ischalgia
- shoulder-arm syndrome
- lumbar syndrome
- cervical syndrome
- paresis of the nervus facialis

4.2. Posology and method of administration

One Neuromultivit film-coated tablet is taken three times daily.

Neuromultivit film-coated tablets are swallowed unchewed with a small amount of liquid after meals.

4.3. Contraindications

- Known hypersensitivity to one of the components.

4.4. Special warning and precautions for use

The administration of a high dosage preparation for more than four weeks should not be carried out due to a possible triggering of neurological symptoms. Neither the clinical impression nor laboratory findings are able to establish clearly a funicular myelosis nor pernicious anemia by the vitamin B₁₂ -preparation.

4.5. Interaction with other medicinal products and other forms of interaction

Concomitant administration of isoniazid, penicillamine or oral contraceptives results in reduced efficacy of vitamin B₆ and hence an enhanced demand of the vitamin.

Vitamin B₆ can reduce the efficacy of L-dopa when used within the same period of time.

4.6. Pregnancy and lactation

Due to limited clinical experience the use of a combined application of vitamin B₁, B₆, and B₁₂ is not recommended during pregnancy or breast feeding.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Non-specific side effects such as nausea, headache and dizziness can seldom occur. Less likely to occur are reactions due to hypersensitivity, which appear chiefly on the skin after administering B₁ or B₁₂. *High doses of vitamin B₆ administered over prolonged periods of time may result in the development of sensory peripheral neuropathy.*

4.9. Overdose

Vitamin B₁, B₆ and B₁₂ are generally non toxic compounds with a wide margin of safety.

Vitamin B₁: When taken orally thiamine is non-toxic even after ingestion of large doses. Isolated clinical reports of toxic reactions to the parenteral administration of thiamine probably represent rare instances of hypersensitivity.

Vitamin B₆: Acute doses of less than 500 mg/day appear to be safe. Chronic administration of pyridoxine doses higher than 500 mg/day for prolonged periods of time (up to 8 years) can result in sensory nerve damage.

Vitamin B₁₂ is non-toxic even after administration of high doses.

Treatment of overdose:

Treatment should be supportive and symptomatic.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: vitamin B1 in combination with vitamin B6, and/or vitamin B12
ATC-Code: A11DB

The active component of vitamin B₁ is thiamine-pyrophosphate, which serves as the coenzyme in the decarboxylation of α -keto acids in the carbohydrate metabolism, much like pyruvate and α -ketoglutarate. Thiamine is detectable in nerve tissue and membrane and can interfere in the biosynthesis of neurotransmitters in neuronal functions.

Pyridoxine is an important coenzyme in metabolizing amino acids and serves as the prosthetic group of important enzymes in nerve tissue. In addition pyridoxine influences the biosynthesis and the concentration of many neurotransmitters such as dopamine, noradrenaline, adrenaline, 5-hydroxytryptamine, histamine and GABA.

Cyanocobalamin influences the specially lively synthesis of nucleic acids in the nervous system and the composition of fatty acids in neural cerebroside and phospholipids.

The active coenzyme methylcobalamin and 5'-desoxyadenosylcobalamin are essential for cell growth and replication processes.

5.2. Pharmacokinetic properties

The absorption of thiamine from the gastrointestinal tract is intensified by ingestion of meals. Thiamine is detectable in almost all bodily tissue and remains unchanged or appears in form of metabolites in urine and feces.

The absorption of pyridoxine out of the intestinal tract takes place quickly and completely. Pyridoxine is absorbed in the red blood cells.

The forms of vitamin B₆, pyridoxal and pyridoxal-phosphate, are bound to serum proteins. The main secretion product in the feces is 4-pyridoxic acid.

The absorption of cyanocobalamin occurs through active and passive mechanisms. After binding to the intrinsic factor, the protein-vitamin complex is absorbed into the ileum. The passive mechanism of diffusion may have an effect by increased supply in the whole small intestine.

Vitamin B₁₂ is bound to the serum protein transcobalamin I - III. The excretion occurs via the urine, bile, and feces.

5.3. Preclinical safety data

Not applicable.

6. Pharmaceutical properties

6.1. List of excipients

Tablet core:

Microcrystalline cellulose, Magnesium stearate, Povidone

Film:

Macrogol 6000, Titanium dioxide, Talc, Hypromellose, Poly-(ethylacrylate-methylmethacrylate)
Dispersion 30%

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months

6.4. Special precautions for storage

Do not store above 25° Celsius. Keep blister(s) in the outer carton, in order to protect from light.

6.5. Nature and contents of container

20 and 100 film-coated tablets

6.6. Instructions for use and handling, and disposal (if appropriate)

No special requirements.

7. Marketing authorisation holder

Lannacher Heilmittel Ges. m. b. H.,
8502 Lannach,
Austria

8. Marketing authorisation number

MA069/00301

9. Date of first authorisation/renewal of authorisation

15th July 2005

10. Date of revision of the text