

B-VITA Capsules



Composition: Each B-VITA Capsule contains:
Thiamine Hydrochloride (Vitamin B1) 100 mg.
Pyridoxine Hydrochloride (Vitamin B6) 100 mg.
Cyanocobalamin (Vitamin B12) 0.5 mg.

Pharmacological Properties:

B-VITA is combination of three vitamins important and essential for the nervous system (B1, B6, B12) in high doses. Each of these vitamins is essential for a normal metabolism in the nerve cell.

Vitamin B1 is involved in the conduction of nerve impulses. Vitamin B6 plays an essential role in the enzymatically controlled neurotransmitter metabolism and it has an analgesic effect. Vitamin B6 deficiency can be associated with peripheral neuritis and neuropathy. Vitamin B12 is involved in the methylation of the myelin basic protein. Vitamin B12 deficiency can result in neurological symptoms like paresthesia, ataxia and others. Moreover, in most of the patient populations such as elderly, diabetic patients and others, deficiency in this group of vitamins can be observed.

Pharmacokinetics:

Vitamin B1: Is absorbed from the GI tract by an active transport system and is widely distributed to most body tissues. It is not stored appreciably in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites (thiamine carboxylic acid and pyrimine).

Vitamin B6: Is quickly absorbed from the intestinal tract and converted to the active form pyridoxal phosphate. It is excreted in the urine mainly as 4-pyridoxic acid.

Vitamin B12: Absorption of cyanocobalamin in healthy people is limited and depends on the concentration of the "internal factor". After absorption from the intestine, vitamin B12 in the serum binds to some proteins such as transcobalamin. Vitamin B12 is stored mainly in the liver. The half-life in plasma is about 5 days, and in the liver is about 1 year.

Indications:

B-VITA is indicated in the treatment of:

- Mono and polyneuropathies e.g.; diabetic, toxic or alcoholic neuropathies.
- Neuritis and neuralgia, especially neck syndrome, shoulder-arm syndrome, lumbago, sciatica, nerve root irritation due to degenerative changes of the vertebral column, herpes zoster.
- For the follow-up treatment of trigeminal neuralgia and for supportive treatment in facial paresis.
- Deficiency or increased need for vitamins B1, B6, and B12.

Contraindications:

- Hypersensitivity to any of the active ingredients or excipients.
- B-VITA should not be used in patients on Levodopa therapy.

Warnings & Precautions:

Patients with long-term neuropathies (6-12 months) are prescribed a median dose of vitamin B6 (greater than 50 mg), which requires regular monitoring (when undergoing long-term treatment).

Pregnancy & Lactation:

Pregnancy: There are no risks associated with using this medicine during pregnancy at the recommended dose.

Lactation: Vitamins B1, B6, and B12 are excreted in breast milk, but no risk of overdosage has been reported in children. In individual cases, high doses of vitamin B6 more than 600 mg per day can affect milk production.

Drug Interactions:

- 5-Fluorouracil inhibits thiamine activation by competitively inhibiting the phosphorylation of thiamine to thiamine pyrophosphate.

- The effect of levodopa may be reduced when vitamin B6 is administered concomitantly.

- Antacids inhibit the absorption of vitamin B1.

- Antacids: Long-term use of gastric acid-reducing agents may result in vitamin B12 deficiency.

- Isoniazid, Cycloserine, Penicillamine, Hydralazine: these drugs can reduce the efficacy of vitamin B6 (pyridoxine).

- Loop Diuretics (Furosemide): In long-term use, the blood level of thiamine may be reduced.

Side Effects:

Side effects are very rare and include: Hypersensitivity reactions such as sweating, tachycardia, skin reactions (e.g. urticaria). Gastrointestinal symptoms, such as nausea, vomiting, diarrhea or abdominal pain, may occur.

Driving & Using Machines:

B-VITA do not affect the capability to drive a vehicle or to operate machinery.

Dosage & Administration:

- Recommended daily dose: One capsule once daily. In individual cases, the dose may be increased to one capsule 3 times daily.

- The capsule should be swallowed whole with plenty of liquid after meals.

- The physician in charge should decide on the duration of administration.

- B-VITA must not be used in children and adolescents.

Overdose:

Symptoms: There is no evidence that B-VITA can cause an overdose if used as recommended. In rare cases, excessive daily doses of vitamin B6 (500 mg or more during more than 5 months) may lead to reversible peripheral sensory neuropathy. However, these effects may generally go away after treatment is stopped.

Treatment: Includes removal of the toxin (through induction of vomiting, gastric lavage). And measures to reduce absorption (administering activated charcoal).

Storage:

Keep out of reach of children. Store below 25 °C.

Packaging:

Each B-VITA carton box contains 20 Capsules in two blister strips.

- A medicament is a product which affects your health, and it's 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 experts in medicine, it's benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
- KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
- Council of Arab Health Ministries - Union of Arab Pharmacies

Revapharma for Pharmaceutical Industries - Idlib - Syria

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المرضى الذين يعانون من اعتلالات عصبية طويلة الأمد (٦-١٢ شهرًا) ويعالجون بجرعات متوسطة من فيتامين ب٦ (أكثر من ٥٠ ملغ)، الأمر الذي يتطلب مراقبة منتظمة (عند الخضوع لعلاج طويل الأمد).