

VOLTAC-B Capsules



Composition:

Each VOLTAC-B Capsule contains:

Thiamine Hydrochloride (vitamin B1)	50 mg.
Pyridoxine Hydrochloride (vitamin B6)	50 mg.
Cyanocobalamin (vitamin B12)	250 mcg.
Diclofenac Sodium	50 mg.

Pharmacological Properties & Mechanism of Action:

VOLTAC-B consists of the participation of three important and essential vitamins for the nervous system (B1, B6, and B12) with diclofenac.

Vitamin B1: Essential for carbohydrate metabolism and maintaining the integrity of nerve fibres.

Vitamin B6: Important in the metabolism of proteins and amino acids and in the synthesis of neurotransmitters in the nervous system.

Vitamin B12: Plays a role in the maturation of nerve cells and maintaining their integrity.

Diclofenac sodium: It is a non-steroidal anti-inflammatory with analgesic and anti-inflammatory properties. It works by inhibiting the synthesis of prostaglandins.

Pharmacokinetics:

Vitamin B1: Is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Vitamin B6: Is absorbed from the gastrointestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

Vitamin B12: It is absorbed from the gastrointestinal tract and is highly bound to plasma proteins. Maximum concentrations in blood and tissues are reached 8-12 hours after a dose. It is stored in the liver, excreted in the bile and undergoes enterohepatic recycling. Part of the dose is also excreted in the urine.

Diclofenac sodium: Diclofenac is completely absorbed after oral administration, reaching peak plasma concentrations after 2 hours. It undergoes metabolism during first-pass hepatic so that only 50% of the drug reaches the systemic circulation in unchanged form. Diclofenac is 99.7% protein bound, primarily to albumin. Diclofenac is metabolized and then excreted as glucuronide and sulfate bound, in the urine (60%) and in the bile.

Indications:

VOLTAC-B is indicated for treatment of:

- Neuritis and neuralgia like cervical syndrome, and sciatica.
- Painful degenerative forms of rheumatism of an inflammatory nature or activated by an inflammation: Arthritis, chronic polyarthritis, ankylosing spondylitis, acute gout attacks.
- Non-articular rheumatism.
- Non-rheumatic inflammatory pain.

Contraindications:

- Hypersensitivity to any of the active ingredients or the excipients.
- In patients with asthma, allergic rhinitis or urticaria associated with previous NSAIDs therapy.
- In patients with peptic ulcer or gastrointestinal bleeding.
- Severe liver and renal failure.
- Severe heart failure (NYHA class IV).

Warnings & Precautions:

- Careful medical monitoring is required in patients with a history of gastric or intestinal ulcer, with gastrointestinal disorders, as well as in patients with liver or kidney damage, hypertension and/or heart failure and in elderly patients.
- If severe pain, in particular in the epigastric region and/or black discoloration of the feces should occur, the doctor should be informed immediately.

- In long-term treatment, blood counts should be monitored, and liver and renal functions evaluated regularly.

- VOLTAC-B should not be administered to children under age of 6 years.

- VOLTAC-B should not indicate in vit B deficiency.

Pregnancy & Lactation:

Pregnancy: VOLTAC-B Capsules are contraindicated during the last trimester of pregnancy. Moreover, during the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary.

Lactation: VOLTAC-B should not be used during breastfeeding.

Drug interactions:

- The effect of levodopa may be reduced if used concomitantly with pyridoxine.
- Diclofenac may increase plasma concentrations of digoxin and lithium.
- Concomitant use of diclofenac with diuretics or antihypertensive drugs (e.g., beta-blockers, ACE inhibitors) may cause a decrease in their antihypertensive effect.
- Concomitant use of diclofenac with corticosteroids, anticoagulants such as warfarin, selective serotonin reuptake inhibitors (SSRIs) or antiplatelet aggregation drugs may increase the risk of ulceration or bleeding.
- Long-term use of anticid medications may lead to vitamin B12 deficiency.

Side Effects:

Gastrointestinal disorders such as nausea, diarrhea, slight gastrointestinal bleeding. In rare cases, headache, insomnia, dizziness, urticaria, and hypersensitivity reactions such as rashes and pruritus.

Driving & Using Machines:

Patients who experience visual disturbances, dizziness, drowsiness, central nervous system disorders, or fatigue while taking NSAIDs should refrain from driving or operating machinery.

Dosage & Administration:

Capsule should be swallowed whole, with some water, during or after meals and dose adjusted by doctor depending on severity of the disease, the recommended dose is:

Adults: 1 capsule (1-3 times a day).

Children over 6 years of age: 2 mg diclofenac per kg body weight distributed over several doses.

Overdose:

Symptoms:

There is no evidence that the B vitamins in VOLTAC-B can cause overdose if used as recommended.

Diclofenac: Symptoms of an overdose of NSAIDs are usually limited to drowsiness, nausea, vomiting, epigastric pain, and gastrointestinal bleeding may occur, but very rarely. Hypertension, acute renal failure, and respiratory depression may occur.

Treatment:

Treatment is mainly symptomatic and supportive. Diuresis may not be helpful in eliminating NSAIDs, including diclofenac, due to high protein binding. Administration of activated charcoal, induction of vomiting, and gastric lavage may be possible after ingestion of a toxic, life-threatening dose.

Storage:

Store at a temperature below 25°C. Keep out of reach of children.

Packaging:

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

*A medication 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 medication.
- Do not repeat the same prescription without consulting your doctor.
- The doctor and the pharmacist experts in medicine, it's benefits and risks.
KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers, Union of Arab Pharmacists

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

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