
UNICOBAL FORTE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for **UNICOBAL FORTE** (Mecobalamin 1500 mcg, Alpha Lipoic Acid 100mg, Folic Acid 1.5 mg & Pyridoxine 3mg Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Mecobalamin:* It works by functioning in the production of a compound called myelin, which covers and protect nerve fibers. Methylcobalamin rejuvenates the damaged neuron. Without enough Methylcobalamin, myelin sheath does not form properly due to which nerve fibers suffers and people experience irreversible nerve damage. An intrinsic factor made in the stomach, must be present in the intestinal tract to allow its proper absorption. *Alpha Lipoic Acid:* Lipoic Acid is generally involved in oxidative decarboxylations of keto acids and is presented as a growth factor for some organisms. *Folic acid:* Folic acid, a biochemically inactive compound, is the precursor for tetrahydrofolic acid and methyl tetrahydrofolate. Tetrahydrofolic acid, methyl tetrahydrofolate, and other folic acid congeners are essential for the maintenance of normal erythropoiesis and are also required cofactors for the synthesis of purine and thymidylate nucleic acids. *Pyridoxine Hydrochloride:* Pyridoxine is converted in erythrocytes to pyridoxal phosphate and to a lesser extent pyridoxamine phosphate, which act as coenzymes for various metabolic functions affecting protein, carbohydrate, and lipid utilization. Pyridoxine is involved in conversion of tryptophan to niacin or serotonin, breakdown of glycogen to glucose-1-phosphate, conversion of oxalate to glycine, synthesis of gamma aminobutyric acid (GABA) within the CNS, and synthesis of heme.

INDICATIONS: UNICOBAL FORTE is indicated for the treatment of diabetic neuropathy.

DOSAGE AND ADMINISTRATION: As directed by the Physician.

CONTRAINDICATION: Hypersensitivity to the active substance, cobalt or to any of the excipients.

WARNINGS & PRECAUTIONS: *Diabetic patients:* In accordance with current clinical practice, some diabetic patients who gain weight on treatment may need to adjust hypoglycaemic medicinal products., *Encephalopathy:* Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate encephalopathy. *Diabetes:* Unicobal Forte can decrease blood sugar levels. Diabetes medications might need to be adjusted by patient's healthcare provider. *Excessive use of alcohol/thiamine deficiency:* Alcohol can lower the amount of thiamine (vitamin B1) in the body. Taking Unicobal Forte when there is a shortage of thiamine might cause serious health problems. *Thyroid disease:* Taking Unicobal Forte might interfere with treatments for under-active or over-active thyroid. *High numbers of red blood cells (polycythemia vera):* The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera. *Abnormal red blood cells (megaloblastic anemia):* Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. However, this can have very serious side effects. Don't attempt Unicobal Forte therapy without close supervision by healthcare provider., *Leber's disease, a hereditary eye disease:* Do not take Unicobal Forte if patient have this disease. It can seriously harm the optic nerve, which might lead to blindness. *Post-surgical stent placement:* Avoid using Unicobal Forte , after receiving a coronary stent. This may increase the risk of blood vessel narrowing.

DRUG INTERACTIONS: Medications for diabetes (Antidiabetes drugs) interacts with Unicobal Forte, Fosphenytoin interacts with Unicobal Forte, Methotrexate interacts with Unicobal Forte, Phenobarbital interacts with Unicobal Forte, Phenytoin interacts with Unicobal Forte, Primidone interacts with Unicobal Forte, Pyrimethamine interacts with Unicobal Forte, Amiodarone interacts with Unicobal Forte, Phenobarbital interacts with Unicobal Forte, Phenytoin interacts with Unicobal Forte, Levodopa interacts with Unicobal Forte, Chloramphenicol interacts with Unicobal Forte.

ADVERSE REACTIONS: Anorexia, nausea, abdominal distension and flatulence Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock) Anaphylactic reaction, People taking alpha-lipoic acid by mouth might get a rash. severe peripheral neuritis, Rash, anorexia, nausea/vomiting and diarrhea, headache, anaphylactoid reaction, hot sensation, diaphoresis.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)