

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

Elmecob OD
(Methylcobalamin Tablets)

COMPOSITION

Each film coated tablets contains

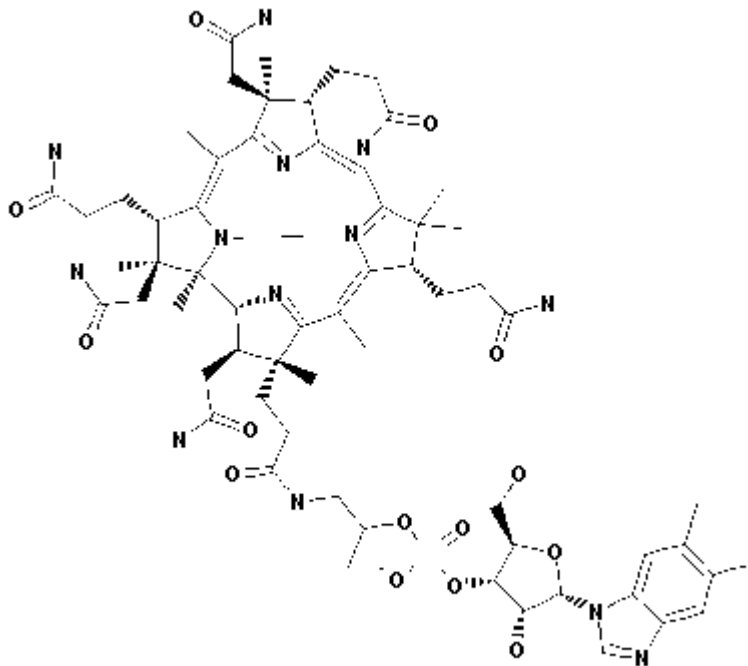
Methylcobalamin 1500microgram

Excipients q.s.

Colors: Lake of Erythrosine and Titanium dioxide IP.

DESCRIPTION

Methylcobalamin or mecobalamin is having molecular weight of 1344.38gram/mol with molecular formula of $C_{63}H_{91}CoN_{13}O_{14}$. It is having a structural formula as follows:



CLINICAL PHARMACOLOGY

Pharmacodynamics

Methylcobalamin is one of the biologically active form of vitamin B12. It acts as coenzymes in nucleic acid synthesis. Mecobalamin is also closely involved with folic acid in several important metabolic pathways. Methylcobalamin (CH_3B_{12}) supports the methionine synthetase reaction, which is essential for normal metabolism of folate.

Pharmacokinetic

It binds to intrinsic factor; a glycoprotein secreted by the gastric mucosa, and is then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. After intranasal dosage, peak plasma concentrations of cyanocobalamin have been reached in 1 to 2 hours. The bioavailability of the intranasal preparation is about 7 to 11% of that by intramuscular injection.

It is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. A parent form -vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B12 diffuses across the placenta and also appears in breast milk.

INDICATIONS

For the treatment & management of:

- Accidents and Trauma.
- Fractures.
- Neuropathies of various etiologies.
- Bell's palsy.
- Hyper homocysteinemia.

CONTRAINDICATION

It is contraindicated in the patients who are having hypersensitivity to active constituents or any of the formulation ingredients.

WARNINGS AND PRECAUTIONS

Should be given with caution in patients suffering from folate deficiency.

The following warnings and precautions suggested with parent form – vitamin B12

- The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera.
- Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Don't attempt vitamin B12 therapy without close supervision by your healthcare provider.
- Do not take vitamin B12 if Leber's disease, a hereditary eye disease. It can seriously harm the optic nerve, which might lead to blindness.

DRUG INTERACTION

The data are unavailable for methylcobalamide drug interaction, however evidences for parent drug – vitamin B12 are as follows

- Absorption from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H₂-antagonists, omeprazole, and colchicine.
- Serum concentrations may be decreased by use of oral contraceptives.

- Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations.
- Parenteral chloramphenicol may attenuate the effect in anaemia.
- Potassium supplements can reduce absorption of vitamin B12 in some people and might contribute to vitamin B12 deficiency.
- Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects. Be sure that your healthcare provider checks your vitamin B12 levels before you start taking folic acid.
- Early research suggests that vitamin C supplements can destroy dietary vitamin B12. It isn't known whether this interaction is important, but to stay on the safe side, take vitamin C supplements at least 2 hours after meals.
- Heavy drinking for at least a two-week period can decrease vitamin B12 absorption from the gastrointestinal tract.

ADVERSE EFFECTS

- Generally, ELMECOB is well tolerated. No toxicity reactions have been reported.
- Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis.
- Polycythemia vera may also be seen.
- Mild transient diarrhea has been seen.
- Rarely itching; transitory exanthema.
- Other adverse effects reported with vitamin B12 are diarrhea, blood clots, itching, serious allergic reactions.

OVERDOSAGE

Evidences are un-available for overdose of methylcobalamine.

DOSAGES AND ADMINISTRATION

Elmecob Tablets: 1 tablet 3-4 times daily at least for 12 weeks. Dose and duration can be adjusted depending on patient's age and symptoms. Elmecob OD Tablets: 1 tablet once daily for 12 weeks Elmecob Injections: 1 injection after every 2-3 days for 4 weeks. To be followed by tablets for 8-12 weeks.

USE IN PREGNANCY, NURSING MOTHER, USE IN CHILDREN AND OLDER PATIENTS

No data available for use of methylcobalamin in special population.

EXPIRY DATE

Do not use later than expiry.

STORAGE

Store in cool dry place, protect from light.

PRESENTATION

5x3x10 Tablets.

MANUFACTURED BY

Windlas healthcare (P) Limited.

Plot no. : 183 & 192,

Mohabewala industrial area,

Dehradun – 248110 (India).

MARKETED BY



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