

MECOVIT 500MCG TABLET

Composition:

Each film-coated tablet contains 500mcg Mecobalamin.

Description:

A white to off white round shaped film coated tablet.

Pharmacodynamic:

Vitamin B12 in the form of mecobalamin is a cofactor in the methionine synthase reaction. The enzyme converts homocysteine to methionine.

Methionine is a precursor of S-adenosylmethionine (S-AdoMet). S-AdoMet is the principal transmethylation agent and is involved in, among many other things, the synthesis of myelin basic protein. Abnormal myelin basic protein resulting in defective myelination, is thought to be responsible for many of the neurological effects of B12 deficiency.

B12 deficiency results in decreased formation of thymidylate acid and purine nucleotides, precursors of DNA synthesis and which are necessary for normal cell division.

Mecobalamin acts to repair damaged nerve tissue in nerve disorder eg, axonal degeneration and demyelination and it is involved in erythroblast maturation, promotion of erythroblast division, and heme synthesis, thus acting to improve the status of the blood in megaloblastic anemia.

Pharmacokinetics:

Tablet: Single-Dose Administration: After oral administration of single dose of 500mcg and 1500mcg of Mecobalamin to healthy adult subjects, dose-related peak plasma concentrations were both achieved after 3 hrs. From 40-80% of the cumulative amount of total B12 recovered in the urine by 24 hrs after oral administration were excreted within the first 8 hrs.

Repeated-Dose Administration: The percentage of increase in the plasma concentration of total B12 were determined in healthy subjects given an oral daily dose of 1500mcg of Mecobalamin for 12 consecutive weeks. The changes in the plasma level were also measured in the same patients for a period of the first 4 weeks after the last administration.

The plasma concentration increased for the first 4 weeks after administration, reaching twice as high as the initial concentration. Therefore it was followed by a gradual increase up to about 280% of that before administration at 12th week of the dosing, and then declined. But it was maintained at approximately 180% of the level before dosing 4 weeks after the last administration.

Vitamin B12 is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Vitamin B12 is stored in the liver and is secreted in the bile and reabsorbed via the enterohepatic circulation. Some of the B12 secreted in the bile is excreted in the feces. Also, oral B12 that is not absorbed is excreted in the feces. Reabsorption of B12 via the enterohepatic circulation requires the intrinsic factor. If the circulating level of B12 exceeds the B12 binding capacity of the blood, the excess is excreted in the urine.

Indication:

Peripheral neuropathies. Megaloblastic anemia due to vitamin B12 deficiency.

Dosage & Administration:

Adult: 1 tablet 3 times a day (1500mcg of Mecobalamin).

The dosage should be adjusted according to age of patient and severity of symptoms.

Route of Administration:

Oral Administration

Contraindication:

Mecobalamin is contraindicated in those hypersensitive to any component of a vitamin B12 containing product.

Warnings and Precaution:

Mecobalamin should if possible not be given to patients without first confirming the diagnosis. Regular monitoring of the blood is advisable.

In patients with folate deficiency, use of doses greater than 10mcg daily may produce a haematological response; indiscriminate use may mask the precise diagnosis.

Effects on ability to drive and use machines

None.

Pregnancy and Lactation:

If you are pregnant or breastfeeding, please consult your doctor or healthcare professional before taking this product.

Interaction:

Absorption of Vitamin B12 from the gastrointestinal tract may be reduced by neomycin, aminosalicic acid, histamine H₂-antagonists, and colchicines.

Serum concentrations may be decreased by concurrent use of oral contraceptives.

Adverse Reaction:

Gastrointestinal: Symptoms eg, anorexia, nausea or diarrhea may occur infrequently.

Dermatological: Skin rash may occur rarely.

Others: Prolonged use of larger doses of Mecobalamin is not recommended to patients whose occupation requires handling of mercury or its compounds.

Overdosage:

There are no reports of vitamin B12 overdosage in the literature.

Presentation:

Blister of 10 tablets. Box of 9, 10 and 50 blisters.

Storage Condition:

Store in dry place below 30°C. Protect from moisture and light.

Manufacturer and Product Registration Holder :

NORIPHARMA SDN. BHD. 200701034604 (792633-A)

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