

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

COBASOFT INJ 1 ml

(Methylcobalamine 500mcg/ml)

COMPOSITION

Each ml contains: Mecobalamin J.P. 500 mcg

Benzyl Alcohol I.P. 2 % w/v (As preservative)

Water for injection I.P. q.s.

Overages are added to compensate the loss on storage

DESCRIPTION

Methylcobalamin is one of the two coenzyme forms of vitamin B12. It is a cofactor in the enzyme methionine synthase which functions to transfer methyl groups for the regeneration of methionine from homocysteine

CLINICAL PHARMACOLOGY

1. Methyl-Cobalamin is a kind of endogenous coenzyme B12 Methyl-Cobalamin plays an important role in transmethylation as a coenzyme of methionine synthetase in the synthesis of methionine from homocysteine.
2. Methyl-Cobalamin is well transported to nerve cell organelles, and promotes nucleic acid and protein synthesis. Methyl-Cobalamin is better transported to nerve cell organelles than cyanocobalamin in rats. It has been shown in experiments with cells from the brain origin and spinal nerve cells in mice to be involved in the synthesis of thymidine from deoxyuridine, promotion of deposited folic acid utilization and metabolism of nucleic acid. Also, Methyl-Cobalamin promotes nucleic acid and protein synthesis in rats more than cobamamide does.

3. Methyl-Cobalamin promotes axonal transport and axonal regeneration. Methyl-Cobalamin normalizes axonal skeletal protein transport in sciatic nerve cells from rat models with streptozotocin-induced diabetes mellitus. It exhibits neuropathologically and electrophysiologically inhibitory effects on nerve degeneration in neuropathies induced by drugs, such as adriamycin, acrylamide, and vincristine (in rats and rabbits), models of axonal degeneration in mice and neuropathies in rats with spontaneous diabetes mellitus.

4. Methyl-Cobalamin promotes myelination (phospholipid synthesis). Methyl-Cobalamin promotes the synthesis of lecithin, the main constituent of medullary sheath lipids, and increases myelination of neurons in rat tissue culture more than cobamamide does.

5. Methyl-Cobalamin restores delayed synaptic transmission and diminished neurotransmitters to normal. Methyl-Cobalamin restores end-plate potential induction early by increasing nerve fiber excitability in the crushed sciatic nerve in rats. In addition, Methyl-Cobalamin normalizes diminished brain tissue levels of acetylcholine in rats fed a choline-deficient diet.

Pharmacokinetics

Pharmacokinetics of intravenous (I.V.) or intramuscular (I.M.) methylcobalamin has not been studied.

When Methyl-Cobalamin was administered orally to healthy adult male volunteers at a single dose of 120 µg and 1,500 µg, the peak serum total vitamin B12 (abbreviated to B12) concentration was reached 3 hr for both doses, and this was dose-dependently. The half-life, increment in the serum total B12 concentration and DAUC by 12 hr after administration were shown in the following figure and table. 40 to 80 percent of the cumulative amount of total B12 excreted in the urine by 24 hr after administration was excreted within the first 8 hrs.

INDICATIONS:

For the treatment of peripheral neuropathies and megaloblastic anemia caused by vitamin B12 deficiency

CONTRAINDICATIONS:

Hypersensitivity to cobalamin products or cobalt.

WARNING AND PRECAUTIONS:

The prolonged use of larger doses of Methyl-Cobalamin is not recommended for patients whose occupation requires the handling of mercury or mercury compounds. Use cautiously with cardiovascular disease, lung disease and hypertension.

DRUG INTERACTIONS:

Metformin, histamine H-2 receptor antagonists (cimetidine, ranitidine, etc), aminoglycosides, colchicine, aminosalicic acid, anticonvulsants and alcohol decrease absorption of vitamin B-12.

Don't use with chloramphenicol.

ADVERSE REACTIONS:

Adverse reactions have been reported in approximately 1% of patients.

Gastrointestinal: Anorexia, Nausea, Vomiting & Diarrhea

Hypersensitivity: Rarely: Rash

OVERDOSAGE:

Methylcobalamin has excellent tolerability and no known toxicity.

Treatment is unlikely to be needed in cases of over dose.

Expiry date: Do not use later than the date of expiry.

Storage: Store below 25°C, Protected from light (Light sensitive product)

Presentation: COBASOFT INJ. is available as ampoule of 1 ml

MARKETED BY:



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