

VITAXON® (MECOBALAMIN)

Tablet & Injection

COMPOSITION:

Vitaxon Tablet 500 mcg:

Each film coated tablet contains:

Mecobalamin JP 500 mcg.

Product Specs.: CCL Pharmaceuticals

Vitaxon Injection 500 mcg:

Each ml contains:

Mecobalamin JP 500 mcg.

Product Specs.: CCL Pharmaceuticals

PHARMACOKINETICS:

Vitaxon tablet (Mecobalamin) after single oral administration of 120-1500 µg acquires dose-dependent peak plasma level within 3.0 hours. 40-80% of the dose is excreted in urine in first 8 hours. Repeated oral administration of 1500 µg for 12 consecutive weeks the serum concentration increased for the first 4 weeks reaching a value twice as high as the initial concentration followed by a gradual increase reaching a peak at approximately 280% of the initial value at the 12th-week. The serum concentration declines after 12 weeks to approximately 180% of the initial 4 weeks level after the last administration. Vitaxon injection (Mecobalamin) after single IM administration acquires a peak plasma level within 0.9 ± 0.1 hours and within 3.0 minutes after IV administration.

The increment in total peak serum level was 22.4 ± 1.1 ng/ml and 85 ± 8.9 ng/ml with AUC at 144 hours as 204.1 ± 12.9 hrs. ng/ml and 358.6 ± 34.4 hrs. ng/ml for IM and IV respectively. Repeated administration of 500 µg for 10 consecutive days the serum total concentration increased from day to day and become 5.3 ± 1.8 ng/ml, about 1.4 times the 24-hour value (3.9 ± 1.2 ng/ml) after 2 days. At 3 days the level reaches to 6.8 ± 1.5 ng/ml, about 1.7 times the 24-hour value and remains constant till last dosing.

Pharmacology:

Vitaxon (Mecobalamin) is an energized intracellular coenzyme-type or vitamin B12 that facilitates a number of in-vivo reduction and transmethylation reactions. It has anabolic effect on the nucleic acid, protein, carbohydrate and fat metabolism. Mecobalamin occurs in the blood, cerebrospinal fluid and is better distributed to nerve tissues than the original vitamin B12 molecule. Vitaxon (Mecobalamin) performs the following potential biological functions in the body.

Triggers up DNA and protien synthesis by supporting methionine synthetase transmethylation reaction by acting as methyl group donor for the recycling of the folate co-factors. Boosts up lecithin synthesis by enhancing the methionine synthetase activity resulting in myelination of the demyelinated medullary nerve sheath.

Normalizes the axonal transportation of skeletal proteins in sciatic nerve cells, inhibits drug induced (i.e. Anticancer) neuropathological and electrophysiological nerve degeneration with spontaneous Diabetes mellitus.

Restores delayed synaptic transmission by restoration of early induction of the endplate potential by increasing nerve fiber excitability threshold. Normalizes the diminished neuronal level of neurotransmitter acetylcholine in the brain.

Promotes erythropoiesis by increasing nucleic acid synthesis in the bone marrow resulting in increased maturation and division of erythroblasts. Improves hematocrite value by increasing red blood cell, white blood count and hemoglobin percentage.

INDICATIONS:

Vitaxon is recommended in the following pathological conditions:

Peripheral neuropathies, sciatica pain, lumbago. Megaloblastic anemias, especially pernicious anemia and other conditions in which the secretion of intrinsic factor is impaired, as in gastric cancer, gastric atrophy, total or even subtotal gastrectomy. It may also be used in anemia of topical sprue, idiopathic steatorrhoea, gluten-induced enteropathy, regional ileitis, ileal resection, malignancies, granulomas, stricture or other structural disorders of ileum.

DOSAGE AND ADMINISTRATION:

Vitaxon tablet three times a day and injection intramuscularly or intravenously on alternative day or as directed by the physician. The dosage and frequency may be adjusted according to the age and the severity of the symptoms.

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After 2 months the dose should be reduced to 1 tablet on alternative day and injection to a single administration at 1-3 month interval as maintenance therapy.

SIDE EFFECTS:

- Pain at the injection site may occur.
- Gastro-intestinal disorders i.e. Anorexia, nausea, vomiting and diarrhea.
- Very rarely headache, sweating and feeling of pyrexia may occur.
- Hypersensitivity reactions like rash and eruption are rare.

CONTRA-INDICATIONS:

Vitaxon is contraindicated in patients with:

- Sensitivity to cobalt or vitamin-B12.
- Leber's disease.
- With high mercurial exposure.

DRUG INTERACTIONS:

Vitaxon injection is incompatible with ascorbic acid, dextrose and phytomenadione, or 5% warfarin sodium solution resulting in loss of injection clarity.

PRECAUTIONS:

Vitaxon tablets may deteriorate and become reddish when exposed to high humid environments. Mecobalamin is highly photosensitive therefore the products should promptly be used after opening the package. Avoid repeated injection at the same site particularly in children. Do not inject into the nerve cell to avoid neurophlebitis. If needle insertion evokes pain or the blood flows back into the syringe, remove the needle and insert it to another place. The drug should not be used if the clinical response to megaloblastic anemia or peripheral neuropathy is unsatisfactory.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

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| Vitaxon Tablet 500 mcg | : | Pack of 3 x 10 tablets. |
| Vitaxon Injection 500 mcg | : | Pack of 2 x 5 ampoules. |

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

خوراک:

برائے ٹیبلٹ: ایک گولی دن میں تین مرتبہ ۲ ماہ کیلئے یا

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

برائے انجکشن: ایک انجکشن ہر دوسرے دن ۲ ماہ کیلئے یا

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:



Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
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