IDAMAN PHARMA MANUFACTURING SDN BHD

CITREX MECOLAMIN 500MCG TABLET

PRODUCT DESCRIPTION
Round,film coated tablet and plain on both sides.
Colour: Pink

Each tablet contains Mecobalamin 500 mcg

Source of Lactose: Bovine

ROUTE OF ADMINISTRATION
Oral

PHARMACODYNAMICS
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 (SAMe). SAMe is the principal transmethylating agent and 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 thymidylic 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 e.g., 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
Single Dose Administration: After oral administration of single dose of 500 mcg and 1500 mcg of Mecobalamin to healthy adult subjects, dose related peak plasma concentrations were both achieved after 3 hours. From 40-80% of the cumulative amount of total B12 recovered in the urine by 24 hours after oral administrations were excreted within the first 8 hours.

Repeated-Dose Administration: The percentage increase in the plasma concentration of total B12 were determined in healthy subjects given an oral daily dose of 1500 mcg 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 dosing, and then declined. But it was maintained by 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 the 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 that is not absorbed is excreted in the feces. Reabsorption of B12 via the enterohepatic circulation requires intrinsic factor. If the circulating level of B12 exceeds the B12 binding capacity of the blood, the excess is excreted in the urine.

INDICATIONS
a) Used for the treatment of peripheral nerve damage.
b) Used for the treatment of megaloblastic anemia due to Vitamin B12 deficiency.

RECOMMENDED DOSE
Adult Dose: Oral administration 1 tablet 3 times daily (total of 1500 mcg of Mecobalamin). The dosage should be adjusted accordingly based on patient's age and the severity of the symptoms.

CONTRAINDICATIONS
Hypersensitivity to Mecobalamin or other components of the formulation. Discontinue if symptoms of hypersensitivity occur.

WARNINGS & PRECAUTION
Mecobalamin should if possible not to 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.

INTERACTIONS WITH OTHER MEDICAMENTS
Absorption of Vitamin B12 from the gastrointestinal tract may be reduced by:
a) Neomycin.
b) Aminosalicylic acid.
c) Histamine H2-antagonist.
d) Cholchicine.

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

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

ADVERSE/SIDE EFFECTS
a) Gastrointestinal: Anorexia, nausea or diarrhea may occur infrequently.
b) Dermatology: Skin rash may occur rarely.
c) Others: headaches, sweating, hot sensation and hypersensitivity to Mecobalamin or any component of the tablet. Prolonged use of larger doses of Mecobalamin is not recommended to patients whose occupation requires handling of mercury or its compound.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

There have been no reports, in the literature, of overdosage with Mecobalamin.

PACK SIZE

Blister pack of 10's:

50 strips of 10 tablets

STORAGE CONDITION

Store below 30°C. Protect from moisture and light.

SHELF LIFE.

2 years from the date of manufacture.

REGISTRATION NUMBER

MAL18046137XZ

KEEP MEDICINES OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult your doctor or your pharmacist.

Revision Number : 01
Revision Date : 05 Sep 2019

Lt-204.01 Product Registration Holder and Manufacturer
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