MECOBALAMIN

GEOCOBALAMIN

Rx 500 mcg/mL Solution for Injection
(I.M. / I.V.)

ANTI ANEMIC

FORMULATION:
Each mL injection contains:
Mecobalamin (Vitamin B12), J.P. .....500 mcg

PRODUCT DESCRIPTION:
Dark red clear solution free from extraneous particles.

INDICATIONS:
To be used in the treatment & prevention of vitamin B12 deficiency.

PHARMACODYNAMICS:
Mecobalamin promotes the metabolic pathways of Nucleic acid, proteins and lipids, through its involvement in the transmethylation reaction; thus it exerts a repairing effect on injured nerve tissues.

PHARMACOKINETICS:
Vitamin B12 substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastro-intestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorbtion syndrome or with disease or abnormality of the gut. Absorption from the gastrointestinal tract can also occur by passive diffusion. Vitamin B12 specifically extensively bounds to specific plasma protein called Transcobalamin; Transcobalamin II appears to be involved in the rapid transport of the cobalamins to the tissues. Vitamin B12 is stored in the liver, excreted in the bile and undergoes enterohepatic recycling; part of an administered 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 in the placenta and also appears in the breast milk.

CONTRAINDICATIONS:
Mecobalamin is contraindicated in patients with known hypersensitivity to Mecobalamin or either ingredient of the drug.

ADVERSE EFFECTS:
Hypersensitivity, Anorexia, nausea vomiting, diarrhea, skin rash seen rarely during oral therapy. Some other more commonly occurring side effects includes headache, sweating, and hot sensation.

REPORTING OF SUSPECTED ADVERSE REACTIONS:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reaction directly to the importer/distributor and/or to FDA: www.fda.gov.ph.

Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

DRUG INTERACTION:
Neomycin, amino salicylic acid, histamine H2-receptor antagonists and Colchicines may reduce the absorption of Mecobalamin from gastrointestinal tract.

DOSAGE & ADMINISTRATION:
Usual daily dose is 1 injection once in a week I.M or I.V for a month.
For Peripheral neuropathies:
The usual dose for adults is 1 ampoule (500mcg of mecobalamin) three times a week, administered intramuscularly or intravenously. The dosage may be adjusted according to the patient's age and symptoms.
For Megaloblastic anemia:
The usual dose for adults is 1 ampoule (500mcg of mecobalamin) a day, administered intramuscularly or intravenously three times a week. After approximately 2 months of medication, the dose should be reduced to a single administration of ampoule at 1 to 3 month intervals for maintenance therapy.

OVERDOSAGE & TREATMENT:
Overdose symptoms such as nausea, vomiting crushing and muscle atrophy have been reported. In such cases seek the advice of the doctor but use of frequent water and cold drinks is recommended.

CAUTION:
Food, Drugs, Devices, and Cosmetics Act Prohibits dispensing without prescripition.

STORAGE:
Store at temperatures not exceeding 30°C.
Protect from light & excessive heat.

AVAILABILITY:
1 mL Amber Glass Ampoule (Box of 10's)

FDA REGISTRATION No.: DRP-7803
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Manufactured by:
GEOFMAN PHARMACEUTICALS
20/23, Korangi Industrial Area, Karachi, Pakistan.

Imported & Distributed by:
SAHAR INTERNATIONAL TRADING INC.
354 Aguirre Ave., Phase-III, BF Homes, Parañaque City.