MECOBALAMIN

MECONEURO®

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

Vitamin

PRODUCT DESCRIPTION :
Mecobalamin (Meconeuro®) 500 mcg / mL Solution for Injection is a red color and clear solution.

FORMULATION :
Each 1 mL ampoule contains :
Mecobalamin …….. 500 mcg

MECHANISM OF ACTIONS :
Biochemically, Mecobalamin is a B12 co-enzyme with an active methyl base. It participates in transmethylation reactions and is the most active of B12 homologues in the body with respect in to nucleic acid, protein, and lipid metabolism. Mecobalamin acts to repair damaged nerve issue in nerve disorders, e.g axonal degeneration and demyelination, and it is involved in erythroblast maturation, promotion of erythroblast division, and heme synthesis, thus Mecobalamin repairs the blood status in megaloblastic anemia condition.

INDICATIONS :
Treatment of peripheral neuropathies, megaloblastic anemia, and other manifestations of Vitamin B12 deficiency.

DOSAGE AND MODE OF ADMINISTRATIONS :
The usual adult dosage is 1 ampoule, equivalent to 500 mcg of Mecobalamin administered IM or IV three times a week. The dosage should be adjusted according to the age of the patient and severity of symptoms.

CONTRAINDICATIONS :
Patients hypersensitive to Mecobalamin.

WARNING AND PRECAUTIONS :
Discontinue medication if there is no response after administration for several months.

DRUG INTERACTIONS :
Absorption of Vitamin B12 from the gastrointestinal tract may be reduced by Neomycin, Aminosalicytic acid, Histamine H2-antagonists, Omeprazole, and Colchicine. Serum concentrations may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations. Parenteral Chloramphenicol may attenuate the effect of vitamin B12 in anemia.

ADVERSE DRUG REACTIONS :
Hypersensitivity : discontinue the administration of this drug if symptoms of hypersensitivity, e.g. eruption, occurs.
Others: pain and induration may sometimes occurs at the site of injection and headache sweating or fever may rarely occur.
Loss of appetite, nausea, diarrhea, or other symptoms of gastrointestinal upset may appear.

STORAGE CONDITION :
Store at temperatures not exceeding 30°C. Protect from light.

PACKAGING AVAILABLE (PACK SIZE) :
1 mL USP Type I amber glass ampoule mounted in PVC tray x 5 ampoules (box of 10 ampoules)

CAUTIONS :
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING :
For suspected adverse drug reaction, report to the FDA : www.fda.gov.ph

REGISTRATION NUMBER :
DRP-7352

DATE OF FIRST AUTHORIZATION :
29 September 2017

DATE OF REVISION OF PACKAGE INSERT :
October 2017

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER :

PROSWEAL Healthcare Inc.

PROSWEAL HEALTHCARE INC.
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NAME AND ADDRESS OF MANUFACTURER :

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LFT/00/1117

Paper of HVS 60 gsm, 100 mm x 230 mm, one column (in one side), one side, one language (English language)