Front Side

210 mm

240 mm

MECOBALAMIN

MECONERV

500 mcg Film Coated Tablet
1 mg Film Coated Tablet
1.5 mg Film Coated Tablet
VITAMIN

PRODUCT NAME:
Meconerv

NAME AND STRENGTH:
Mecobalamin (Methylcobalamin) Tablets USP 500 mcg
Mecobalamin (Methylcobalamin) Tablets USP 1 mg
Mecobalamin (Methylcobalamin) Tablets USP 1.5 mg

PHARMACOLOGIC CATEGORY:
Vitamin

PRODUCT DESCRIPTION:
Light pink colored, circular, biconvex, film coated tablets

FORMULATION/COMPOSITION:
Each film-coated tablet contains:
Mecobalamin (Methylcobalamin) USP ..... 500 mcg

Each film-coated tablet contains:
Mecobalamin (Methylcobalamin) USP ..... 1 mg

Each film-coated tablet contains:
Mecobalamin (Methylcobalamin) USP ..... 1.5 mg

PHARMACODYNAMICS/PHARMACOKINETICS:
Pharmacodynamics:
Methylcobalamin (Mecobalamin, MeCbl), is one of the two biologically active vitamin B12. Mecobalamin acts as an important cofactor in the reaction of one class of the B12 enzymes, the Methyltransferases. The B12-dependent Methyltransferases play an important role in amino acid metabolism in many organisms as well as in one-carbon metabolism and CO2 fixation in anaerobic microbes. Among them, methionine synthase is the most extensively studied B12-dependent Methyltransferases in humans. As the cofactor of the enzyme methionine synthase, Mecobalamin functions to catalyze the transfer of the methyl group from methylene tetrahydrofolate to homocysteine (Hcy) to form methionine and tetrahydrofolate.
Because Mecobalamin acts as an important cofactor of methionine synthesis, supplements of Mecobalamin enhance the efficiency of the demethylation pathway, consequently accelerating Hcy consumption and reducing its concentration. Thus, lowering homocysteine concentrations to the normal range (4 – 15 µmol/l) seems to be an effective therapeutic method in decreasing the risks of the diseases mentioned above.

Pharmacokinetics:
Absorption
Evidence indicates Methylcobalamin is utilized more efficiently than cyanocobalamin to increase levels of one of the coenzyme forms of vitamin B12. Experiments have demonstrated similar absorption of Methylcobalamin following oral administration. The quantity of cobalamin detected following a small oral dose of Mecobalamin is similar to the amount detected following the administration of cyanocobalamin, but significantly more cobalamins accumulates in liver tissue, which is associated with Mecobalamin intake.
Distribution and Metabolism
Cobalamin circulates in plasma bound to two carrier proteins: transcobalamins (TC) and haptocorrin. TC is a 43-kDa non-glycoprotein that transfers cobalamin from the intestine into the blood stream and then into all the cells of the body. Cobalamin-saturated transcobalamins (holoTC) constitutes 6 – 20% of total plasma cobalamin. The unsaturated TC is called apotranscobalamin, which constitutes the major part of TC. Additionally, total homocysteine (tHcy) and methylmalonyl acid are considered to be two functional markers of vitamin B 12 status in adults.
Excretion
Human urinary excretion of Methylcobalamin is about one third that of a similar dose of cyanocobalamin, indicating substantially greater tissue retention.

INDICATIONS:
Methylcobalamin is used in the prevention and treatment of following conditions and symptoms:
Peripheral Neuropathy
Megaloblastic Anemia
Diabetic neuropath
Arthritis
Sclerosis

DOSAGE AND MODE ROUTE OF ADMINISTRATION:
The dose of Methylcobalamin is recommend on the basis of several factors such as medical condition, severity of the condition, age, allergic history and response of the body to the first dose. Usually, the suggested dose for adult is 3 tablets a day which is 1.5 mg of Vitamin B12. If it is administered in intravenous way then the usual dose is 500 mcg thrice a week. An individual should strictly adhere to the suggested dosage. Any dose alteration should only be done only after consulting a medical practitioner. In case of a missed dose, the medicine should be taken as soon as one remembers. If it is already time for the next dose, then the usual dose should be continued instead of overdosing to compensate for the missed dose. If an individual overdoses on Methylcobalamin, one should seek medical attention without any delay; as overdose of Methylcobalamin may result in severe symptoms. Use of Methylcobalamin is not recommended for paediatric use. Hence, it is advised to consult a pediatrician before providing the medicine to children.

CONTRAINDICATIONS &PRECAUTION(S), WARNING(S):
Methylcobalamin is contraindicated in patients who are hypersensitive to Methylcobalamin or any of the components of this product.

PRECAUTIONS & WARNINGS:
Following points must be kept in mind while taking Methylcobalamin 500 MCG Tablet :
- Pregnant women should avoid the use of medicine after first trimester unless asked by a medical practitioner.
- The medicine is found to be safe for use by breastfeeding women. However, a medical practitioner should be consulted in advance to avoid any risk of side effects.
- The medicine may affect liver; hence, dosage adjustment may be required.
- Patients with a history of allergy to Methylcobalamin or its ingredient should avoid inform the medical practitioner beforehand.
- An individual with recent history of gastrointestinal surgery should avoid the use of Methylcobalamin.
- People coming in contact with Mercury should practice caution while using Methylcobalamin.
- Elderly people may not have capacity to absorb the Methylcobalamin through intestines. In such case appropriate dose adjustment and clinical monitoring is recommended.

PREGNANCY AND LACTATION:
Pregnancy:
Pregnant women should avoid the use of medicine after first trimester unless asked by a medical practitioner.

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

PHARMACODE READING DIRECTION

14 (L) x 8 (H) mm

PHARMACODE READING DIRECTION

329

Back Side

210 mm

240 mm

Lactation:
The medicine is found to be safe for use by breastfeeding women. However, a medical practitioner should be consulted in advance to avoid any risk of side effects.

INTERACTIONS:
Two drugs when taken together may result in drug interaction. The interaction may lead to neutralization of effect of either of the medicines or an undesirable effect.
Here is a possible list of possible interactions:
Antacids: Consuming Antacids along with Methylcobalamin may interfere with its absorption. Hence, it is advised to ask for an appropriate dose adjustment or a suitable alternative from a medical practitioner.
Folic acid: Supplements of Folic acid can mask the symptoms of anemia caused due to vitamin B12 deficiency. Hence, it is advised to consult the medical practitioner to ensure the correct supplement is being consumed.
Antibiotics: Use of antibiotics along with Methylcobalamin reduces the absorption and induces reversible mal-absorption of Methylcobalamin.
Hence, it is advised to inform the medical practitioner about the use of antibiotics beforehand.
To avoid any risk of drug interaction, it is advised to inform the medical practitioner about the ongoing medication (herbal medicine, vitamin supplements, etc.) beforehand.
Interaction with alcohol
Consumption of alcohol along with Methylcobalamin can interfere with the absorption of the medicine. This can result in undesired effects.
Hence, it is not advised to consume alcohol along with Methylcobalamin.
Interaction with Diseases
Methylcobalamin when consumed in case of certain medical conditions can result in worsening of the present medical condition or severe side effects.
Hence, it is advised to inform the medical practitioner about any medical condition.
Methylcobalamin can interact with the following disease:
Leber's disease: It is a rare genetic disorder and use of Methylcobalamin should be prohibited in this condition.
It is advised to inform the doctor in advance about this medical condition.

ADVERSE EFFECTS:
Apart from the desired effect, consumption of Methylcobalamin may result in some undesired effects as well. These undesired effects vary from person to person depending on the clinical condition and ongoing medications.
Abdominal pain
Nausea and vomiting
Vaginal bleeding
Skin rash
Redness of skin
Vaginal infection
A headache
Loss of appetite
Diarrhea
Dizziness
Decreased appetite
Chest pain and discomfort

OVERDOSAGE AND TREATMENT:
If an individual overdoses on Methylcobalamin, one should seek medical attention without any delay; as overdose of Methylcobalamin may result in severe symptoms

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

DOSAGE FORMS AND PACKAGING AVAILABLE:
Mecobalamin (Methylcobalamin) Tablets USP 500 mcg:
Alu/PVC/PVDC Blister pack x10's (Box of 30's)
Mecobalamin (Methylcobalamin) Tablets USP 1 mg:
Alu-Amber PVC/PVDC Blister pack x10's (Box of 30's)
Mecobalamin (Methylcobalamin) Tablets USP 1.5 mg:
Alu-Amber PVC/PVDC Blister pack x10's (Box of 30's)

INSTRUCTIONS AND SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL (IF APPLICABLE):
Not Applicable

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
Marketing Authorization Holder
Brown & Burk Philippines Inc
U-501, 5/F., SEDCCO 1 Bldg., 120 Rada cor.,
Legaspi Sts., Legaspi Village, Makati City, Philippines

NAME AND ADDRESS OF MANUFACTURER:
MICRO LABS LIMITED
92, Sipcot Industrial Complex,
Hosur – 635 126 (T.N), India.

CAUTION STATEMENT:
FOODS, DRUGS, DEVICES, AND COSMETICS ACT PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

ADR REPORTING STATEMENT:
FOR SUSPECTED ADVERSE DRUG REACTION, REPORT TO THE FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of Adverse Drug Reaction.

REGISTRATION NUMBER:
Meconerv 500 mcg: DR-XY48323
Meconerv 1 mg: DR-XY48322
Meconerv 1.5 mg: DR-XY48321

DATE OF FIRST AUTHORIZATION:
-

DATE OF REVISION OF PACKAGE INSERT:
July 2019

EXG-ML01I-1815

35 mm | 35 mm | 35 mm | 35 mm | 35 mm | 35 mm

Paper 35 to 60 gsm

Size : 210 (L) x 240 (H) mm
Drg. No.: W0990005916Z-000
Folding size: 35 x 120 mm
Carton size: 36 x 30 x 75 mm

MICRO LABS LIMITED, BANGALORE, INDIA

1	Product Name	Meconerv
2	Strength	500 mcg, 1 mg and 1.5 mg
3	Component	Leaflet
4	Category	Export - Philippines
5	Dimension	210 (L) x 240 (H) mm
6	Artwork Code	EXG-ML01I-1815
7	Pharma Code	329
8	Reason for Change	New Artwork

Colours Used

BLACK

	Prepared by (DTP)	Checked by (PD)	Approved by			
			Head CQA	Head Production/ Packing (Site)	Head QC (Site)	Head QA (Site)
Sign	Kantharaju L.					
Date	18-11-2022					