

# TOPWELLNESS MYCOBAL 500 mcg Tablet

## CONTENT

Each tablet contains 500mcg methylcobalamin

### Excipients:

Lactose, Corn starch, Polyvinylpyrrolidone K30, Microcrystalline cellulose, Magnesium stearate, Silicon Dioxide, Sodium Starch Glycolate

## DESCRIPTION

Mycobal is a white uncoated tablet, round shape, 10mm diameter, embossed with NOVA on one side, no scoring. Odor: No odor, Taste: Plain taste

## 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 is 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 eg, 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.

## PHARMCOKINETICS

Single-Dose Administration: After oral administration of single dose of 500mcg and 1500mcg of Mecobalamin to healthy adult subjects, dose-related peak plasma concentrations were both achieved after 3 hrs. From 40-80% of the cumulative amount of total B12 recovered in the urine by 24 hrs after oral administration were excreted within the first 8 hrs.

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

## INDICATION

For the treatment of numbness, pain and paralysis due to peripheral neuropathies such as diabetic neuropathy and polyneuritis. For the treatment of megaloblastic anaemia due to Vitamin B12 deficiency.

## RECOMMENDED DOSAGE

### For oral administration

Adults: The initial dose is 500mcg (1 tablet) taken 3 times a day after meal or as directed by your doctor/ pharmacists.

## CONTRAINDICATIONS

Contraindicated in those hypersensitive to any component of vitamin B12 containing product.

## WARNING / PRECAUTIONS

- Keep out of reach of children (*Jauhkan daripada capaian kanak-kanak*)
- Please consult your doctor/pharmacist before using this product if you are on other medicines. There may be a potential for interactions or side effects.

## DRUG INTERACTION

Some medicines and Mycobal may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Medicines for diabetes e.g., metformin
- Antibiotics e.g., chloramphenicol, neomycin, amino salicylic acid and aminoglycosides group e.g., gentamicin
- Medicine for gastric ulcers e.g., cimetidine, ranitidine
- Medicines for epilepsy e.g., phenobarbital
- Colchicine, for gout

## PREGNANCY AND LACTATION

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

## SIDE EFFECTS

Like many medicines, Mycobal may cause side effects in some patients, particularly when you first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

- Anorexia
- Nausea
- Vomiting
- Diarrhoea

The above list is the more common side effects of the medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Skin rashes or urticaria

The above list is the rare side effects of the medicine.

Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers à Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

## SYMPTOM & TREATMENT OF OVERDOSE

Methylcobalamin is well tolerable with no known toxicity. Treatment is unlikely to be needed in cases of overdose.

## EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Taking Mycobal is unlikely to affect your ability on driving and operating machinery.

## PACKING / PACK SIZES

30's/60's/90's per White HDPE Plastic Bottle with Green PP Plastic Cap.

## STORAGE CONDITION

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

## SHELF LIFE

3 Years

## NAME AND ADDRESS OF MANUFACTURER

Nova Laboratories Sdn Bhd  
Lot 708, Nova Avenue, Batu 4,  
43950 Sungai Pelek, Sepang,  
Selangor, Malaysia.

## PRODUCT REGISTRATION HOLDER

Topwellness Healthcare Sdn. Bhd.  
Unit 11-4, No. 2, Block 2,  
Jalan Setia Prima (S) U13/S,  
Setia Alam, Seksyen U13,  
40170 Shah Alam, Selangor.

Revised Date: 30-3-2025