

ERACOBAL TABLET

COMPOSITION :

Each film coated tablet contains :

Methylcobalamin		1500mcg.
Vitamin B1	I.P.	10mg.
Pyridoxine HCL	I.P.	3mg.
Folic acid	I.P.	10mg.

METHYLCOBALAMIN

DESCRIPTION:

Methylcobalamin is a form of vitamin B₁₂. It is one of four cobalamin compounds that the human body is able to metabolize. A cobalamin compound contains a central cobalt ion, with one of four particular groups attached to its upper ion which are methyl group.

Methylcobalamin is produced by bacteria in our body. These bacteria are present in the human liver, but the cobalamin compounds produced in the body are not usable, and are expelled out with feces.

Methylcobalamin plays a key role in the normal functioning of the brain and nervous system, and for the formation of blood. We need methylcobalamin for the healthy development and sustenance of our circulatory, immune and nervous systems. Methylcobalamin is the only active form of Vitamin B₁₂ in the brain outside the mitochondrion. It is normally involved in the metabolism of every cell of the human body, especially affecting DNA synthesis and regulation, but also fatty acid synthesis and energy production.

Methylcobalamin can be used to prevent or treat pathology arising from a lack of Vitamin B₁₂ (Vitamin B₁₂ deficiency), such as pernicious anemia. It is also used in the treatment of peripheral neuropathy, diabetic neuropathy and as a preliminary treatment for amyotrophic lateral sclerosis.

MECHANISM OF ACTION :

Methylcobalamin is the neurologically active form of Vitamin B₁₂ and occurs as a water-soluble vitamin in the body. It is a cofactor in the enzyme methionine synthase, which functions to transfer methyl groups for the regeneration of methionine from homocysteine. In anemia, Methylcobalamin increases erythrocyte production by promoting nucleic acid synthesis in the bone marrow and by promoting maturation and division of erythrocytes.

Methylcobalamin, folic acid, Vitamin B₆ and other methyl donors control homocysteine levels. An excess of homocysteine is associated with an increased risk of heart disease, stroke, osteoporosis and Alzheimer's disease.

Absorption : Peak plasma concentrations after 3 hr (oral); 0.9 hr (IM); 3 min (IV).

Excretion : Via urine.

METHYLCOBALAMIN WITH VIT.B & FOLIC ACID :

Homocysteine can be converted to methionine/cysteine which is an essential amino acid with the aid of B vitamins. Homocysteine levels can be elevated by deficiencies of folic acid (B9), pyridoxine (B6) or Methylcobalamin.

Elevated homocysteine levels have been associated with many degenerative diseases including heart disease, arteriosclerosis and osteoporosis. Methylcobalamin and folic acid work synergistically to recycle homocysteine back to methionine by the methylation cycle. Therefore, Methylcobalamin, folic acid and B6 are now getting new consideration as the role of homocysteine in heart and cardiovascular health is being recognized.

CLINICAL USAGE :

Methylcobalamin can be used to prevent or treat pathology arising from a lack of vitamin B₁₂, Peripheral Neuropathy, Diabetic Neuropathy, Low Back Pain, Homocysteine and pernicious anemia . It is also used in the treatment for amyotrophic lateral sclerosis.

Bell's palsy : Evidence suggests methylcobalamin dramatically increased the recovery time for facial nerve function in Bell's palsy.

Diabetic Neuropathy : Orally administered of methylcobalamin 1500 mcg./day for 3-4 months shows significant improvement in burning sensations, numbness, loss of sensation, and muscle cramps.

Methylcobalamin therapy also shows improvement in reflexes, vibration sense, lower motor neuron weakness, and sensitivity to pain. (Ref.: **Yaqub BA, Siddique A, Sulimani R. Effects of methylcobalamin on diabetic neuropathy. Clin Neurol Neurosurg 1992; 94:105-111.**)

Heart Rate Variability: Variation of heart rate is a means of detecting the relative activity and balance of the sympathetic and parasympathetic nervous systems. Methylcobalamin produces improvements in several components variation of heart rate, suggesting a balancing effect on the nervous system. (Ref.: **Yoshioka K, Tanaka K. Effect of methylcobalamin on diabetic autonomic neuropathy as assessed by power spectral analysis of heart rate variations. Horm Metab Res 1995; 27:43-44.**)

Homocysteinemia: Elevated levels of homocysteine can be corrected by methylcobalamin administration. It reduces the level of elevated homocysteine from a mean value of 14.7 to 10.2 nmol / ml. following parenteral treatment with methylcobalamin. (Ref.: **Araki A, Sako Y, Ito H. Plasma homocysteine concentrations in Japanese patients with non-insulin-dependent diabetes mellitus: effect of parenteral methylcobalamin treatment. Atherosclerosis 1993;103:149-157.**)

Sleep Disturbances: Methylcobalamin plays a promising role in the treatment of a variety of sleep-wake disorders. Although the exact mechanism of action of methylcobalamin is not yet identified in the correction of sleep disturbances. It is may be possible because of methylcobalamin is needed for the synthesis of melatonin, since the biosynthetic formation of melatonin requires the donation of a methyl group. Supplementation of methylcobalamin appears to have a great role of ability to modulate melatonin secretion, enhance light-sensitivity, normalize circadian rhythms, and normalize sleep-wake rhythm. (Ref.: **Uchiyama M, Mayer G, Okawa M, Meier - Ewert K. Effects of vitamin B12 on human circadian body temperature rhythm. Neurosci Lett 1995; 192:1-4.**)

Other usage : All of the B vitamins are known for reducing stress factors in the body and mind, and are widely taken as daily supplements all over the world. In addition to this benefit, Methylcobalamin has shown promise as a cancer therapy and provides powerful immunity effects.

DOSAGE :

The dosage for methylcobalamin to gain clinical effect is 1500-6000 mcg. / Day or how much should take will depend on the age and condition of the patient.

No significant therapeutic advantage occurred from dosages exceeding of this 1500-6000 mcg. /Day.

SIDE EFFECTS :

Common side effects :

Headache, Itching, Swelling, Nervousness and anxiousness, Involuntary or uncontrollable movements, mild adverse effects like anorexia, nausea, vomiting and diarrhea.

Serious side effects :

1. Low levels of potassium in the blood.
2. Congestive heart failure.
3. Clots in the arms and legs.
4. Life-threatening allergic reaction called anaphylaxis, in which you may have trouble breathing, your tongue swells and/or throat closes up, and your skin breaks out into hives
5. Fluid building up in the lungs.

SAFETY AND TOLERABILITY :

Methylcobalamin has excellent tolerability and no known toxicity.

DRUG INTERECTIONS :

It's always important to share with the doctor and pharmacist all of the medications the patient is taking. Some medications that have serious interactions with Vitamin B12 are:
Chlorambucil (A chemotherapy drug), Omeprazole (PPI), Colchicine (A medication used to treat gout).

OVERDOSE :

If a patient suspects an overdose of vitamin B₁₂, contact a poison control center or emergency room immediately.

MISSED DOSE :

If a patient miss a dose of should take it as soon as you remember.

If it's almost time for the next dose, skip the missed dose and take the next dose at the regular time.

STORAGE INSTRUCTIONS :

Store below 30° C away from direct sunlight.

PRESENTATION :

Eracobal Tab. is available 1*10 in an Alu-Alu strip and 10 strips in a carton.