

Mebal

(MECOBALAMIN)

500mcg
Tablets U.S.P.
500mcg/ml
I.M. / I.V.
Injection

DESCRIPTION

Mebal is the preparation of mecobalamin (Methylcobalamin). It is the one and only homologue of vitamin B12, found in the brain that participates in transmethylation as a B12 containing coenzyme and plays a fundamental role in protein synthesis and stimulates methionine synthesis from homocysteine and helps to restore normal levels of DNA and RNAs in nerve cells. It also enhances the formation of lecithin (another major component of the myelin sheath).

PHYSICO-CHEMISTRY

Nonproprietary name: Mecobalamin (JAN, INN)

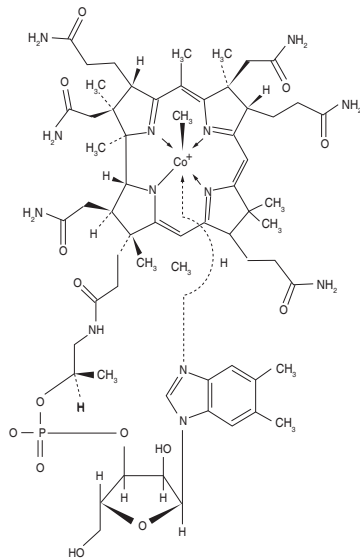
Chemical name:

Coa-[α -(5,6-Dimethyl-1H-benzimidazol-1-yl)]-Co-methylcobamide

Molecular formula: C₆₃H₉₁CoN₁₃O₁₄P

Molecular weight: 1,344.38

Structural formula:



COMPOSITION:

Mebal Tablets U.S.P. 500mcg:

Each sugar-coated tablet contains:

Mecobalamin J.P.500mcg

Mebal Injection 500mcg/ml :

Each ml contains: Mecobalamin J.P.500mcg

INDICATIONS

Mebal is indicated in

Peripheral neuropathies

Diabetic retinopathy

Diabetic neuropathy

Multiple sclerosis

Parkinson's disease

Entrapment neuropathy

Vertebral syndrome

Lumbago

Alzheimer's disease

Drug induced neuropathy

Nerve compression syndrome

Intercostal neuralgia

Amyotrophic lateral sclerosis

Bell's palsy

For injection:

Peripheral neuropathies

Megaloblastic anemia caused by vitamin B12 deficiency

DOSAGE AND ADMINISTRATION

Tablets 500mcg: The usual adult dosage for oral use is 3 tablets (1,500mcg of mecobalamin) daily divided into three doses. The dosage may be adjusted depending on the patient's age and symptoms.

Injection 500mcg:

• **Peripheral neuropathies** The usual dosage for adults is 1 ampoule (500mcg of mecobalamin) daily, administered intramuscularly or intravenously 3 times a week. The dosage may be adjusted depending on the patient's age and symptoms.

• **Megaloblastic anemia** The usual dosage for adults is 1 ampoule (500mcg of mecobalamin) daily, administered intramuscularly or intravenously 3 times a week. After about 2 months of medication, the dose should be reduced to a single administration of 1 ampoule at 1 to 3 months intervals for maintenance therapy.

PHARMACOKINETICS:

1. Single-dose administration: When Mecobalamin was administered orally to healthy adult male volunteers at single doses of 120 µg and 1,500mcg (note) during fasting, the peak serum total vitamin B12 (abbreviated to

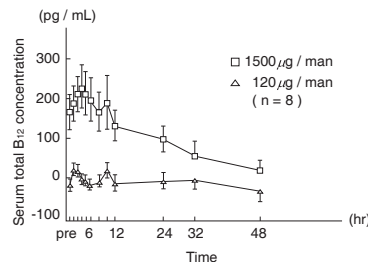
B12) concentration was reached after 3 hrs for both doses, and this was dose-dependent. The half-life, increment in the serum total B12 concentration and AUC₀₋₁₂ by 12 hrs after administration are shown in the following figure and table. Forty to eighty percent of the cumulative amount of total B12 excreted in the urine by 24 hrs after administration was excreted within the first 8 hrs. 2) Note) A single dose of 1,500 µg is unapproved.

Dose	t _{max} (hr)	C _{max} (pg/mL)	ΔC _{max} (pg/mL)	ΔC _{max} (%)	ΔAUC ₀₋₁₂ ¹ (pg/hr/mL)	t _{1/2} ² (hr)
120µg	2.8±0.2	743 ± 47	37±15	5.1±2.1	168 ±58	N.A.
1500µg	3.6±0.5	972 ± 55	255±51	36.0±7.9	2033 ±510	12.5

Mean±S.E., n=8

*1 Calculated by the trapezoidal method from the increment in observed 12hr values, as compared to pre-drug values

*2 Calculated from the average of 24-48 hr values



Increment in total serum B₁₂ concentration

PRECAUTIONS

1. Adverse Reactions

Adverse reactions were reported in 146 of 15,180 patients (0.96%). (At the end of the investigation for incidence of adverse reactions)

	5% > ≥0.1%	<0.1%
Gastrointestinal	Anorexia, nausea/vomiting and diarrhea	
Hypersensitivity ⁽²⁰⁰⁸⁾		Rash

(Note) In the event of such symptoms, treatment should be discontinued.

2. **Precautions concerning Use:** Caution in handing over drug (tablets) For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to use. [It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal

mucosa, causing perforation and resulting in serious complications such as mediastinitis.]

3. **Other Precautions:** The prolonged use of larger doses of Mecobalamin is not recommended for patients whose occupation requires the handling of mercury or mercury compounds.

INSTRUCTIONS:

Mebal Tablets 500mcg

Dosage as directed by the physician.

Store below 30°C.

Protect from heat, light and moisture.

Preserve in tight, light-resistant container.

Keep all medicines out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

Mebal Injection 500mcg/ml

Dosage as directed by the physician.

Store below 30°C.

Protect from heat and light.

Keep all medicines out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

Light sensitive, the ampoule should be opened immediately before using.

PRESENTATION:

Mebal (Mecobalamin) 500mcg tablets U.S.P. are available in 3x10's.

Mebal (Mecobalamin) 500mcg injection available in amber glass ampoule packed in ALU/PVC blister pack of 10 ampoules (2x5's).

Manufactured for:

DANEEN Daneen Pharma (Pvt.) Ltd.

— PHARMA —

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Manufactured by:

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