



24-03-2022

1st Copy

210mm

Mabil[®] Tablets/Injection

(Mecobalamin)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Mabil[®] 500mcg Tablets
Each film coated tablet contains:
Mecobalamin JP 500mcg

Mabil[®] 500mcg/ml Injection
Each ml contains:
Mecobalamin JP..... 500mcg

PHARMACEUTICAL FORM

Tablet / Injection

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

- Peripheral neuropathies
- Megaloblastic anaemia caused by vitamin B₁₂ deficiency.

POSLOGY AND METHOD OF ADMINISTRATION:

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

Injection:

Peripheral neuropathies: The usual dosage for adults is 1 ampoule (500µg of mecobalamin) a day administered intramuscularly or intravenously three times a week. The dosage may be adjusted depending on the patient's age and symptoms.

Megaloblastic anaemia: The usual dosage for adults is 1 ampoule (500µg of mecobalamin) per day, 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.

CONTRAINDICATIONS:

Hypersensitivity to any form of vitamin B₁₂.

SPECIAL WARNINGS AND PRECAUTIONS:

Tablets: Should not be administered for extensive periods (months) to patients who show no clinical response.

- Prolonged use of larger doses are not recommended for patients whose occupation requires handling mercury or its compounds.

Injection: Should not be used aimlessly for more than one month unless it is effective.

- The prolonged use of larger doses of Mecobalamin is not recommended for patients whose occupation requires the handling of mercury or its compounds.

Although the haematological symptoms of B₁₂ deficiency and folate deficiency are similar, it is important to distinguish between them since the use of folate alone in B₁₂-deficient megaloblastic anaemia can improve haematological symptoms without preventing aggravation of accompanying neurological symptoms, and may lead to severe nervous system sequelae such as subacute combined degeneration of the spinal cord.

- Use of doses greater than 10µg daily may produce a haematological response in patients with folate deficiency and indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B₁₂ deficiency.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

- Absorption of vitamin B₁₂ from the gastrointestinal tract may be reduced by neomycin, aminosalicilic 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.

PREGNANCY AND LACTATION:

Injection:

Pregnancy: Clinical studies have been done on pregnant women and no harmful effects have been reported. Mecobalamin with the approved dosage can be used during pregnancy.

Lactation: It has been shown that mecobalamin is excreted in the milk of lactating rats.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not known

UNDESIRABLE EFFECTS:

- Rash, anorexia, nausea/vomiting, diarrhoea, headache. In the event of such symptoms, treatment should be discontinued.
- Pain/induration at the site of intramuscular injection.

OVERDOSE:

Injection: Experience to date with deliberate or accidental overdose is limited. No specific antidote is known. As in any case of overdose, treatment should be symptomatic and general supportive measures should be utilised.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES:

Therapeutic Classification: Mecobalamin; belongs to the class of vitamin B₁₂ (cyanocobalamin and analogues). Used in the treatment of anaemia.

ATC code: B03BA05.

Mechanism of Action:

Mecobalamin is a kind of endogenous coenzyme B₁₂: As a coenzyme of methionine synthetase, mecobalamin plays an important role in transmethylation in the synthesis of methionine from homocysteine.

Mecobalamin is well transported to nerve cell organelles, and promotes nucleic acid and protein synthesis.

Mecobalamin promotes axonal transport and axonal regeneration: Mecobalamin normalizes axonal skeletal protein transport in sciatic nerve cells. Mecobalamin exhibits neuropathologically and electrophysiologically inhibitory effects on nerve degeneration in neuropathies induced by drugs, such as adriamycin, acrylamide, and vincristine (in rats and rabbits), models of axonal degeneration in mice and neuropathies in rats with spontaneous diabetes mellitus.

Mecobalamin promotes myelination (phospholipid synthesis): Mecobalamin promotes the synthesis of lecithin which is the main constituent of medullary sheath lipid.

Mecobalamin restores delayed synaptic transmission and diminished neurotransmitters back to normal: Mecobalamin restores end-plate potential induction early by increasing nerve fiber excitability in the crushed sciatic nerve in rats. In addition, mecobalamin normalizes diminished levels of acetylcholine in brain tissue of rats fed with a choline-deficient diet.

PHARMACOKINETIC PROPERTIES:

Absorption: Vitamin B₁₂ substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy.

Distribution: 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. Vitamin B₁₂ diffuses across the placenta and also appears in breast milk.

120mm



24-03-2022
1st Copy

210mm

Excretion: Vitamin B₁₂ is excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means.
40-80% of the cumulative amount of total vitamin B₁₂ excreted in the urine by 24 hrs after single-dose administration was excreted within the first 8 hrs.

Elimination half-life: 12.5 hrs (single-dose oral administration; calculated from the average of 24-48 hour values).

SHELF LIFE

See expiry on the pack.

AVAILABILITY

Mabil[®] 500mcg tablets in a pack of 30's

Mabil[®] 500mcg/ml injection in a pack of 10's

INSTRUCTIONS

Dosage: As advised by the physician.

To be sold on the prescription of registered medical practitioner.

Keep out of reach of children.

Avoid exposure to heat, light, humidity and freezing.

Store between 15 to 30°C.

Improper storage may deteriorate the medicine.

Injection should not be used if container is leaking, solution is cloudy or it contains undissolved particle(s).

STORAGE AND HANDLING OF INJECTION:

Caution: This product is packaged in LPP (light protective packs) to ensure quality during storage. The LPP should be opened immediately before using.

Storage: This product should be stored in LPP, between 15 to 30°C (If ampoules are kept out of the LPP, the drug will decompose upon exposure to light so that the drug content in the ampoule will decrease).

Expiration date: This product should be used before the expiration date on the package or label.

میل ٹیبلٹ / انجکشن
(میکوبالامین)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو گرمی، روشنی، نمی اور ہتھمد ہونے سے محفوظ ۱۵ سے ۳۰

ڈگری سینٹی گریڈ کے درمیان میں رکھیں درندہ خراب ہو جائیگی۔

دوا کو روشنی سے محفوظ رکھیں تاکہ دوا کی تاثیر برقرار رہے۔

انجکشن کے لیک ہونے، دھندلا ہونے یا اس میں کوئی غیر حل پذیر شے

نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔

Manufactured by:

SAMI Pharmaceuticals (Pvt.) Ltd.

F-95, S.I.T.E., Karachi-Pakistan

www.samipharmapk.com

Mfg. Lic. No. 000072

2000005420

R.N-08/NA/03/2022

120mm