

#### **Composition**:

Each ml Contains

Mecobalamin 500 mcg

#### Pharmacokinetic properties:

Mecobalamin 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. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. After intranasal dosage, peak plasma concentrations of cyanocobalamin have been reached in 1 to 2 hours. The bioavailability of the intranasal preparation is about 7 to 11% of that by intramuscular injection. Mecobalamin is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Mecobalamin is stored in the liver, 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. Mecobalamin diffuses across the placenta and also appears in breast milk.

# **Mechanism of Action**

Mecobalamin –

- Enhances synthesis of proteins in nerve cells
- promotes myelinization
- axonal regeneration
- Helps in generation of enzyme methionine synthase regeneration of methionine from homocysteine.
- Restores diminished neurotransmitter (Acetylcholine) levels.





#### Other pharmacodynamic properties:

Mecobalamin as a coenzyme of methionine synthetase, 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.

Experiments in rats show that mecobalamin is better transported to nerve cell organelles than cyanocobalamin and promotes nucleic acid and protein synthesis more than cobamamide does. Experiments with cells from the brain origin and spinal nerve cells in rats also show mecobalamin to be involved in the synthesis of thymidine from deoxyuridine, promotion of deposited folic acid utilization and metabolism of nucleic acid. It promotes axonal transport and axonal regeneration. It 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. It promotes the synthesis of lecithin which is the main constituent of medullary sheath lipid. It also increases myelination of neurons in rat tissue culture more than cobamamide does. It restores delayed synaptic transmission and diminished neurotransmitters back to normal. It promotes the maturation and division of erythroblasts, thereby alleviating anaemia. It brings about a rapid recovery of diminished red blood cell, haemoglobin, and haematocrit in vitamin B-12 deficient animals.

# Indication:

Nurite injection is indicated in patients with:

- Peripheral neuropathies
- Dementia
- Alcoholic neuropathy
- Drug induced neuropathy
- Trigeminal and occupational neuralgia



- Parkinson's disease
- Bell's palsy
- Megaloblastic anaemia
- Cancer
- Male impotence
- Hyperhomocysteinemia
- Sleep disturbances

### **Contraindication:**

Nurite Injection is contraindicated in patients with Hypersensitivity to Mecobalamin or other components of the formulation.

# **Drug Interaction:**

- Absorption of Mecobalamin from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole, and colchicine.
- Serum concentrations may be decreased by use of oral contraceptives.
- Parenteral chloramphenicol may attenuate the effect of Mecobalamin in anaemia.
- Consumption of alcohol in large quantities can reduce the absorption of Vitamin B12 from the intestine.

# Adverse effects:

Anaphylactic reactions such as decrease in blood pressure or dyspnea may occur. Patient should be monitored after administration of dose.

# Warnings and Precautions:

- This product should not be used aimlessly for more than one month unless it is effective.
- Use of this product should be discontinued if symptoms of hypersensitivity, such as rashes, occur.
- Pain and induration may occur infrequently at the site of intramuscular injection.
- Headache, diaphoresis or hot sensation may occur rarely.
- Mecobalamin is susceptible to photolysis. It must be used promptly after the package is opened and care must be taken not to expose the ampoule to direct light.

# Use in special population:

- 1. Pediatric: Not to be used in newly born or premature infants.
- 2. Geriatric: Few elderly patients may have a reduced capacity to absorb this medicine through the intestine. Appropriate dose adjustments and frequent clinical monitoring are necessary for such patients.
- 3. Liver impairment: Use with caution.
- 4. Renal failure: Use with caution.
- 5. Pregnancy and lactation: Nurite injection is not recommended for use in pregnant women unless necessary. All the risks and benefits should be discussed with the doctor



before taking this medicine. There are no data available for Mecobalamin to be used in lactating women. However, since vitamin B12 is distributed into breast milk, The American Academy of Pediatrics considers its use to be usually compatible with breast feeding.

#### **Dosage:**

As directed by physician.

### **Presentation:**

Nurite injections are available in 1ml ampoules.

#### Storage and handling:

Store in cool, dry and dark place. Protect from light and heat.

