

Subneuro[®]-NT

(Methylcobalamin 1500mcg + Pregabalin 75mg + Nortriptyline 10mg Uncoated Tablets)

Composition:

Each film coated bilayered tablet contains:

Methylcobalamin IP.....1500 mcg

Pregabalin IP... 75mg (In Sustained Release form)

Nortriptyline IP..... 10mg

Excipients...q.s.

Clinical Pharmacology:

Methylcobalamin is an active form of vitamin B12 that helps in synthesis of methionine and S-adenosylmethionine. It is required for integrity of myelin, neuronal function, proper red blood cell formation and DNA synthesis. The largest group of vitamin B12 deficiency is found in typical vegetarians all over the world, which can be alleviated with its analogue Methylcobalamin. It is a beneficial drug to most of the common disorders like cardiovascular disorders, diabetes, anemia, hyperhomocysteinemia and degenerative disorders. Methylcobalamin helps in the synthesis of neuronal lipids, regeneration of axonal nerves and has neuroprotective activity, which promote neurons to function in proper way and thus improves Alzheimer disease, Parkinsonism, Dementia and neuropathic syndromes. It is an approved treatment for peripheral neuropathy.

Pregabalin is structurally related to the antiepileptic drug gabapentin and the site of action of both drugs is similar, the alpha2-delta (alpha2-delta) protein, an auxiliary subunit of voltage-gated calcium channels. Pregabalin subtly reduces the synaptic release of several neurotransmitters, apparently by binding to alpha2-delta subunits, and possibly accounting for its actions in vivo to reduce neuronal excitability and seizures.

Nortriptyline is not a monoamine oxidase inhibitor. It inhibits the activity of such diverse agents as histamine, 5-hydroxytryptamine, and acetylcholine. It increases the pressor effect of norepinephrine but blocks the pressor response of phenethylamine. Studies suggest that Nortriptyline interferes with the transport, release, and storage of catecholamines. Operant conditioning techniques in rats and pigeons suggest that Nortriptyline has a combination of stimulant and depressant properties.

Indications:

- Central & peripheral neuropathy.
- Post herpetic neuralgia.
- Drug induced nerve damage.
- Post traumatic neuropathy.
- Generalised anxiety disorders.
- Neuropathic pain associated with diabetic peripheral neuropathy
- Neuropathic pain associated with spinal cord injury

Contraindications:

- Hypersensitivity to methylcobalamin or other components of the formulation.
- Known hypersensitivity to pregabalin or any of its components.
- Known hypersensitivity to Nortriptyline or any of its components
- Nortriptyline and other tricyclic antidepressants are contraindicated in the acute recovery phase following myocardial infarction.

Precautions and Warnings:

- Vitamin B12 concentrations must be monitored. Patients with declining or abnormally low vitamin B12 concentrations should be switched back to intramuscular vitamin B12 injections
- Effectiveness in patients with nasal pathology or with other concomitant intranasal drugs has not been determined
- Pregabalin may cause dizziness and somnolence and impair patients' ability to drive or operate machinery.
- Cardiovascular patients with preexisting cardiovascular disease may be especially sensitive to nortriptyline. Hypertensive episodes have occurred during surgery in patients receiving tricyclic antidepressants, and the drugs should be discontinued several days prior to selective surgery.
- Adverse CNS and neuromuscular effects occur frequently.

Drug Interactions:

- Absorption of vitamin B12 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.
- Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations.

- Administration of reserpine during therapy with a tricyclic antidepressant has been shown to produce a “stimulating” effect in some depressed patients.

Adverse effects:

- Dermatologic Effects: Rash: In the event of such symptoms, treatment should be discontinued.
- Gastrointestinal Effects: Anorexia, nausea/vomiting and diarrhea.
- Neurologic Effects (Central nervous system): Headache.

Overdosage:

There have been no reports, in the literature, of overdosage with mecobalamin.

Route of administration: Oral.

Type of tablet: Film coated Bilayered Tablet.

Dosage:

As directed by the Physician.

SCHEDULE H PRESCRIPTION DRUG CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Storage: Store in cool, dry & dark place, protected from light & moisture.

Tablet should be swallowed whole not to be chewed or crushed.

Keep the medicine out of reach of children.

Presentation: Subneuro-NT Sublingual Tablet is available as 10x10 Tablet.

Marketed By:



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