

NEVRAMIN[®] TABLETS

Preparation of Fursultiamine, B₆ and B₁₂

COMPOSITION:-

Each tablet contains

Fursultiamine Hydrochloride or Thiamine Tetrahydrofurfuryl Disulfide Hydrochloride (equivalent to Fursultiamine or TTFD (Vitamin B ₁ derivative)	54.58 mg 50 mg)
Pyridoxine hydrochloride (Vitamin B ₆ HCl)	250.0 mg
Cyanocobalamin (Vitamin B ₁₂)	250.0 mcg

DESCRIPTION:-

Nevramin[®] Tablet is a combined preparation of above ingredients available in the form of a pink, sugar-coated tablet.

PHARMACODYNAMICS & PHARMACOKINETICS:-

1) Fursultiamine

Compared with the conventional Vitamin B₁, fursultiamine is taken up in higher concentration into the cells and produces a large amount of cocarboxylase to fill the metabolic pool for Vitamin B₁, physiologically and biochemically. Fursultiamine improves neuro-functional and myocardial metabolic disorders related to Vitamin B₁ deficiency or metabolic disorders.

I) Improving Effect on Neuro-Functional Disorders

Vitamin B₁ plays an important role in maintaining the normal morphological condition of nerve tissues. It has been found that Vitamin B₁ is released and consumed at the impulse conduction along the nerve axons and cocarboxylase is responsible for energy generation in the nerve cells, which depend largely upon sugar metabolism. Fursultiamine is transferred into nerve tissues, and has been shown to have a promotive effect on the proliferation of nerve cell (in vitro), nerve regeneration (in rabbits), and to increase the action potential of the skeletal muscles (in rats). It also improves disorders of nervous functions related to Vitamin B₁ deficiency or metabolic disorders.

II) Improving Effect on Disorders of Myocardial Metabolism

Compared with Vitamin B₁, fursultiamine is taken up well by myocardium cells, and is present almost exclusively, in the form of cocarboxylase in the myocardium (in rats). It has shown to have an improving effect on disorders of myocardial metabolism in the anesthetized dog, and the mechanism is thought to be due to conversion to cocarboxylase in the myocardium.

III) Stimulating Effect on Peristalsis of the Intestine

Fursultiamine has a stimulating effect on intestinal peristalsis (dogs). It has been suggested that this effect might be attributed to the action on the excitatory neurons in the Auerbach's plexus, which are involved in the control of intestinal motility.

Vitamin B₁ has been shown to hardly have such a stimulating effect.

2) Pyridoxine

Pyridoxine, pyridoxal, and pyridoxamine are readily absorbed from the gastrointestinal tract. The principal excretory product when any of the three of the Vitamin is fed to man is 4-pyridoxic acid, formed by the action of hepatic aldehyde oxidase on free pyridoxal. Administration of pyridoxine and pyridoxamine also results in an increased excretion of pyridoxal in man, indicating that both compounds may be first transformed, directly or indirectly, to pyridoxal, which is then oxidized to 4-pyridoxic acid.

3) Cyanocobalamin

Once absorbed, Vitamin B₁₂ binds to transcobalamin II, a plasma β -globulin, for transport to tissues. Two other transcobalamins (I and II) are also present in plasma; their concentrations are related to the rate of turnover of granulocytes. They may represent intracellular storage proteins that are released with cell death. Vitamin B₁₂ bound to transcobalamin II is rapidly cleared from plasma and is preferentially distributed to hepatic parenchymal cells. The liver is thus a storage depot for other tissues. In the normal adult, as much as 90% of the body's stores of Vitamin B₁₂, from 1 to 10mg, is in the liver. Vitamin B₁₂ is stored as the active coenzyme with a turnover rate of 0.05 to 0.2% per day or 0.5 to 8 mcg per day, depending on the size of the body stores.

INDICATIONS:-

Polyneuritis

Anemic conditions: Pernicious anemia, parasitic anemia.

Deficiency of Vitamin B₁, Vitamin B₆, Vitamin B₁₂.

DOSAGE AND ADMINISTRATION:-

Usually, take 1 to 3 tablets of Nevramin[®] tablets a day orally after meals. Swallow without chewing, together with a glass of water or lukewarm water. The dosage should be adjusted according to the patient's age and conditions.

CONTRAINDICATIONS:-

Hypersensitivity: Hypersensitive reactions, such as eruptions, may occur occasionally, and pruritis on rare occasion. If these symptoms occur, NEVRAMIN[®] tablets should be discontinued.

WARNINGS AND PRECAUTIONS:-

Indications and Recommended Dosage should be adhere to.

Nevramin[®] Tablets will not interfere with the capability of driving a car or operating heavy machinery.

Nevramin[®] Tablets should not be used desultorily over a period of one month if the intended therapeutic effects are not observed.

INTERACTIONS WITH OTHER MEDICAMENTS:-

Concurrent use with levodopa is not recommended since levodopa's antiparkinsonian effects are reversed. (By Vitamin B₆).

PREGNANCY AND LACTATION:-

Not reported.

ADVERSE EFFECTS / UNDESIRABLE EFFECTS:-

If the following reactions occur, Nevramin[®] Tablets should be discontinued and consult your doctor or pharmacist.

- Nausea, vomiting, anorexia, gastric discomfort, abdominal distention or diarrhea may infrequently occur. Stomach pain or oral dryness may rarely occur.
- Symptom, such as insomnia or pollakiuria, may rarely occur.

OVERDOSE AND TREATMENT:-

Discontinue the medication when abnormal symptoms appear.

STORAGE CONDITIONS:-

- 1) Store away from light at the temperature below 30 °C.
- 2) Keep out of reach of children
- 3) Do not store in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- 4) Keep the bottle tightly closed.

DOSAGE FORMS AND PACKAGING AVAILABLE:-

30 sheets in cartons (10T/sheet)

MANUFACTURED BY:-

Interthai Pharmaceutical Manufacturing Limited
Bangkok, Thailand

For Takeda (Thailand), Ltd.
Bangkok, Thailand.

LICENSED BY:-

Takeda Pharmaceutical Company Limited
Osaka, Japan

DISTRIBUTED BY:-

For Malaysia:
Luen Wah Medical Co. Sdn. Bhd.,
No. 43G & 43-1F, The Highway Centre,
Jalan 51/205, 46050 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

For Singapore:
Luen Wah Medical Co. (S) Pte. Ltd.
40 North Canal Road,
Singapore 059296.

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