

shine[®] NEUROBINE FILM COATED TABLET

Ingredient(s):

Each tablet contains:

Thiamine mononitrate	100mg
Pyridoxine HCl	200mg
Cyanocobalamin	0.2mg

Pharmacodynamics:

Thiamine combines with ATP to form the coenzyme, thiamine diphosphate required in carbohydrates metabolism and transketolation reactions to enable pyruvic acids to enter Krebs Citric Acid cycle.

Pyridoxine is converted in erythrocytes to pyridoxal phosphate and to a lesser extent pyridoxamine phosphate, which act as coenzymes for various metabolic functions affecting protein, carbohydrate, and lipid utilization. Pyridoxine is involved in conversion of tryptophan to niacin or serotonin, breakdown of glycogen to glucose-1-phosphate, conversion of oxalate to glycine, synthesis of gamma aminobutyric acid (GABA) within the CNS, and synthesis of heme.

Cyanocobalamin acts as a coenzyme for various metabolic function, including fat and carbohydrate metabolism and protein synthesis. It is necessary for growth, cell replication, haematopoiesis and nucleoprotein and myelin synthesis, largely due to its effects on metabolism of methionine, folic acid and malonic acid.

Pharmacokinetics:

Small amounts of thiamine are well absorbed from the gastro-intestinal tract following oral administration, but the absorption of doses larger than about 5mg is limited. It is also rapidly absorbed following intramuscular administration. It is widely distributed to most body tissues, and appears in breast milk. Within the cell thiamine is mostly present as the diphosphate. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine as unchanged thiamine or as metabolites. Pyridoxine, pyridoxal, and pyridoxamine are readily absorbed from the gastro-intestinal tract following oral administration and are converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is oxidation to 4-pyridoxic acid and other inactive metabolites which are excreted in the urine. As the dose increases, proportionally greater amounts are excreted unchanged in the urine. Vitamin B12 substances bind to intrinsic factor; a glycoprotein secreted by the gastric mucosa, and is then actively absorbed from the gastro-intestinal 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. Vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of an administered 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. Vitamin B12 diffuses across the placenta and also appears in breast milk.

Indication(s):

Mononeuropathies & polyneuropathies eg diabetic, alcoholic & toxic neuropathies. Neuritis & neuralgia especially cervical syndrome, shoulder-arm syndrome, lumbago, sciatica, root irritation due to degenerative changes of the vertebral column. Deficiency or raised requirements of vitamin B1, B6 & B12.

Dosage and Administration:

1-3 tablets daily as initial, supportive or follow up measure to parenteral therapy.

Route of Administration: Oral

Contraindication(s):

1. Cyanocobalamin should if possible, not to be given to patients with suspected Vitamin B12 deficiency (without first confirming the diagnosis), patient with Leber's disease or tobacco amblyopia and should not be used to treat megaloblastic anaemia of pregnancy.
2. Neurobine Film Coated Tablet is contraindicated for use in cases with known hypersensitivity to any of its ingredients.

Side Effect(s) / Adverse Reaction(s):

Incidence rare; Thiamine can cause anaphylactic reaction (coughing; difficulty in swallowing, hives, itching of skin, swelling of face, lips, or eyelids, wheezing or difficulty in breathing) usually after large intravenous dose.

Pyridoxine in high doses taken for several months has caused severe sensory neuropathy, progressing from unstable gait and numb feet to numbness to clumsiness of hands.

Cyanocobalamin can cause anaphylactic reaction (skin rash, itching, wheezing) while incidence less frequent are diarrhea and itching of skin.

Precaution(s) / Warning(s):

Nil

Pregnancy and Lactation:

Taking excessive amounts of multivitamin and mineral supplement may be harmful to the mother and/or foetus and should be avoided. Cyanocobalamin is excreted in the breast milk. Thiamine widely distributed to most body tissues and appears in breast milk. Pyridoxine can cross the placenta and also appears in breast milk.

Interactions with Other Medicaments:

High vitamin B6 dose decrease action of L-dopa.

Symptoms and Treatment for Overdosage, and Antidote(s):

1. Doses of 200 mg per day for over a month have been reported to produce a pyridoxine dependency syndrome. Meanwhile high doses of pyridoxine (2-6 g/day) taken for several months have caused a severe sensory neuropathy. This condition seems to be reversible on withdrawal of pyridoxine.
2. Administration of Cyanocobalamin greater than 10µg daily may produce a haematological response in patients with folate deficiency. Indiscriminate use may mask the precise diagnosis.
3. Since there is no specific antidote, treatment should be symptomatic and supportive and may include the following:
 - a) To decrease absorption: Induction of emesis or use of gastric lavage to empty the stomach
 - b) Supportive care: Maintenance of adequate hydration.
4. Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

Shelf-Life:

2 years from the date of manufacture.

Storage Condition(s):

Store at temperature below 30°C. Protect from light and moisture.

Product Description and Packing(s):

A reddish pink color film coated round tablet, one side impressed with a mark



Blister pack of 10's x 10 and 10's x 100.



Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (192593 U)
 Lot 3, 5 & 7, Jalan P/7, Section 13,
 Kawasan Perindustrian Bandar Baru Bangi,
 43000 Kajang, Selangor Darul Ehsan, Malaysia.
 Ordering Line: 1 800 88 3027
 Product Info: 1 800 88 3679

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