

# ‘MPI’ PYRIDOXINE TABLETS 10MG

## **NAME AND STRENGTH OF ACTIVE INGREDIENT:**

Each tablet contains:

Pyridoxine HCl .....10mg

## **PRODUCT DESCRIPTION:**

A white, flat of diameter 6mm round tablet with ‘MPI’ logo.

## **PHARMACODYNAMICS:**

Pyridoxine is converted to the active forms of the vitamin, pyridoxal phosphate and pyridoxamine phosphate, which act as coenzyme for various metabolic function affecting protein, carbohydrate and lipid metabolism. The active forms of the vitamin are involved in transamination of amino acids and in the conversion of tryptophan to niacin or serotonin. Pyridoxine appears to be essential in the synthesis of  $\gamma$ -aminobutyric acid (GABA) within CNS and in the synthesis of heme.

## **PHARMACOKINETICS:**

Pyridoxine is readily absorbed from the gastro-intestinal tract (mainly jejunum) following oral administration and are converted to the active forms of 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. Pyridoxal crosses the placenta and also appears in breast milk. The biological half-life of pyridoxine appears to be 15-20 days. Elimination: Renal (almost entirely as metabolites).

## **INDICATION:**

Used as a Health Supplement.

## **RECOMMENDED DOSAGE:**

Usual adult dose: 1-2 tablets per day for 3 weeks followed by a multivitamin preparation.

## **ROUTE OF ADMINISTRATION:**

Oral

## **CONTRAINDICATIONS:**

Pyridoxine should not be used to patients with a history of sensitivity to the vitamin.

## **WARNINGS AND PRECAUTIONS:**

The pyridoxine tablet should be swallowed whole, not chewed. Long-term large doses may induce nerve damage (neuropathy).

Keep out of reach of children. Jauhi dari kanak-kanak.

## **INTERACTIONS WITH OTHER MEDICAMENTS:**

Pyridoxine should not be administered in dosages >5mg daily to patients receiving Levodopa alone, unless concomitant administration of Carbidopa with Levodopa.

## **PREGNANCY AND LACTATION:**

### **Pregnancy**

Problems in humans have not been documented with intake of normal daily requirements. However, exposure to large doses of pyridoxine in utero may result in a pyridoxine dependency syndrome in the neonate.

### **Lactation**

There is insufficient information on the excretion of pyridoxine in human milk. A risk to the breastfed child cannot be excluded.

## **SIDE EFFECTS**

Water-soluble vitamins seldom cause toxicity in persons with normal renal function. Doses of 200mg per day for over 30 days have been reported to produce a pyridoxine dependency syndrome. Chronic administration of large dosages (2-6g daily for several months) has been associated with adverse neurologic effect, progressing from unstable gait and numb feet to numbness and clumsiness of hands. This condition seems to be reversible on withdrawal of pyridoxine, although some residual weakness has been observed.

## **SYMPTOMS AND TREATMENT OF OVERDOSE:**

Although pyridoxine has generally been considered relatively nontoxic, long term (i.e. 2 months or longer) administration of large dosage (i.e. usually 2g or more daily) of pyridoxine can cause sensory neuropathy or neuronopathy syndromes. Following

discontinuance of pyridoxine, neurologic dysfunction gradually improved, and following a prolonged follow-up period, the patients reportedly recovered satisfactorily.

**EFFECT ON ABILITY TO DRIVE AND USE MACHINE:**

Pyridoxine may cause sudden fall asleep during daily activities. Do not drive or operate any machinery.

**STORAGE CONDITIONS:**

Keep in original packaging or amber container. Store below 30°C. Protect from light, heat and moisture.

**DOSAGE FORMS AND PACKAGING AVAILABLE:**

Dosage form: Tablet

Packing size: Blister Pack: 100 x 10's

Plastic Container: 1000's

**NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:**

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN. BHD. (101323-U)

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas, Pulau Pinang, Malaysia.

**DATE OF REVISION:**

25/08/25