



## 1.5.2 Container Labelling

### LEAFLET:

#### PYRIDOXINE TABLETS BP 100 mg

##### Composition:

Each uncoated tablet contains:  
Pyridoxine Hydrochloride BP 100 mg  
Excipients ..... q.s

##### Clinical Pharmacology:

Pyridoxine is indicated for adults and children over 12 years old in the treatment of isoniazid-induced peripheral neuritis and pyridoxine deficiency states.

##### Pharmacodynamic properties

Pyridoxine is one of three similar compounds that may be referred to as Vitamin B6. The other two compounds are pyridoxal and pyridoxamine. Pyridoxine, converted to pyridoxal phosphate, is a co-enzyme for transamination and is involved in many metabolic processes.

##### Pharmacokinetic properties

Pyridoxine is readily absorbed from the gastrointestinal tract following oral administration and is converted to the active forms of pyridoxal phosphate and pyridoxamine phosphate, which are stored in the liver. The principal excretory product is 4-pyridoxic acid, which is formed by the action of hepatic aldehyde oxidase on free pyridoxal. Pyridoxine crosses the placenta and also appears in breast milk.

##### Indications & Dosage:

Deficiency states

- ▶ BY MOUTH
- ▶ Adult: 20-50 mg 1-3 times a day

Isoniazid-induced neuropathy (prophylaxis)

- ▶ BY MOUTH
- ▶ Adult: 10-20 mg daily

Isoniazid-induced neuropathy (treatment)

- ▶ BY MOUTH
- ▶ Adult: 50 mg 3 times a day

Idiopathic sideroblastic anaemia

- ▶ BY MOUTH
  - ▶ Adult: 100-400 mg daily in divided doses
- Prevention of penicillamine-induced neuropathy in

Wilson's disease

- ▶ BY MOUTH
- ▶ Adult: 20 mg daily

Premenstrual syndrome

- ▶ BY MOUTH
- ▶ Adult: 50-100 mg daily

##### Warnings and precautions:

- If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.
- PREGNANCY: There are no or limited amount of data from the use of pyridoxine in pregnant women. Studies in animals have shown reproductive toxicity. Pyridoxine is not recommended during the first trimester of pregnancy.
- BREASTFEEDING: There is insufficient information on the excretion of pyridoxine in human milk. A risk to the breastfed child cannot be excluded.

##### Interaction with other medicinal products and other forms of interaction

- Pyridoxine antagonizes the therapeutic effect of levodopa when it is used without a dopa-decarboxylase inhibitor.
- Larger doses of pyridoxine can cause a reduction in serum phenytoin and phenobarbitone levels in some patients.
- Pyridoxine requirements have been reported to be increased by oral contraceptives, hydralazine, isoniazid, cycloserine and penicillamine.

##### Side Effects & Adverse Drug reaction:

- None at recommended dosages. Large daily doses taken over a prolonged period can cause the development of severe peripheral neuropathy.

##### Storage:

Store under normal storage condition (15°C to 30°C)  
Protect from light.  
Keep all Medicines out of reach of children.

##### Presentation:

Blister Pack of 10 x 10 Tablets  
Jar Pack of 1000 Tablets  
Jar Pack of 100 Tablets



Manufactured in India by:

AGOG PHARMA LTD.

Plot No. 33, Sector - II, The Vasai Taluka Indl.  
Co-op. Estate Ltd., Vasai (East), Dist. Thane, INDIA.

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