

## Product Summary

### 1. Trade Name of the Medicinal Product

Pyridoxine Hydrochloride Tablets 50mg

### 2. Qualitative and Quantitative Composition

Pyridoxine Hydrochloride BP 50.0 mg

### 3. Pharmaceutical Form

Tablet

## Clinical Particulars

### 4.1. Therapeutic Indications

Isoniazide-induced peripheral neuritis.  
Idiopathic sideroblastic anaemia  
Deficiency states

### 4.2. Posology and Method of Administration

#### Isoniazid-Induced Peripheral Neuritis:

*Adults:*

Treatment - 50mg three times daily.

Prophylaxis - 10mg daily (for which purpose this presentation is not suitable).

*Children:*

This presentation is not recommended.

#### Idiopathic Sideroblastic Anaemia:

*Adults:*

100-400mg Daily in divided doses

*Children:*

This presentation is not recommended.

#### Deficiency States:

*Adults:*

50 - 150mg daily in divided doses.

*Children:*

This presentation is not recommended.

*Elderly:* Dosage requirements appear to be similar to those for young adults.

**4.3. Contra-indications**

Inhibits lactation and should not be given to nursing mothers.

**4.4. Special Warnings and Precautions for Use**

None stated.

**4.5. Interactions with other Medicaments and other forms of Interaction**

Reduces the effect of levadopa

**4.6. Pregnancy and Lactation**

Inhibits lactation and should not be given to nursing mothers.

**4.7. Effects on Ability to Drive and Use Machines**

None stated

**4.8. Undesirable Effects**

Although pyridoxine does not usually cause any side effects at usual doses, concerns about possible severe peripheral neuropathy resulting from prolonged use of pyridoxine at high dosage have not yet been resolved.

**4.9. Overdose**

Excessive dosage may produce headache; no treatment is necessary.

## **Pharmacological Properties**

### **5.1. Pharmacodynamic Properties**

Pyridoxine hydrochloride is vitamin B6. It is converted to pyridoxal phosphate which is the co-enzyme for a variety of metabolic transformations. It is essential for human nutrition.

### **5.2. Pharmacokinetic Properties**

Pyridoxine hydrochloride is absorbed in the GI-tract and is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. It is excreted in the urine as 4- pyridoxic acid. It crosses the placental barrier and appears in breast milk.

### **5.3. Preclinical Safety Data**

Not applicable.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Dicalcium phosphate, starch, sodium lauryl sulphate and magnesium stearate.

### **6.2. Incompatibilities**

None stated

### **6.3. Shelf life**

3 years

### **6.4. Special precautions for storage**

Store in a cool dry place protected from light below 25°C.

**6.5. Nature and Contents of Container**

Snap-safe containers of 25, 50 & 100 tablets. Tempertainer of 1000 tablets.  
Blister packs of 28 tablets.

**6.6. Instruction for use and handling**

Not applicable

**7. MARKETING AUTHORISATION HOLDER**

Forley Generics Ltd  
NLA Tower  
12-16 Addiscombe Road  
Croydon  
CR0 0XT  
United Kingdom

**8. MARKETING AUTHORIZATION NUMBER**

PL 16201/0019

**9 Date of the first authorisation or renewal**

06/10/2005

**10 Date of revision of the text**

06/10/2005