

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

Carton

### **1. Name of the medicinal product**

[TB413 trade name]\*

Pyridoxine hydrochloride 10 mg tablets

### **2. Statement of active substance**

Each tablet contains 10 mg Pyridoxine hydrochloride

### **3. List of excipients**

See patient information leaflet

### **4. Pharmaceutical form and contents**

Uncoated tablets

10 x10 tablets

50 x10 tablets

100x10 tablets

### **5. Method and route of administration**

Oral use

Read the patient information leaflet before use.

### **6. Special warning that the medicinal product must be stored out of the reach and sight of children**

Keep this medicine out of the sight and reach of children.

### **7. Other special warning(s), if necessary**

### **8. Expiry date**

EXP {MM/YYYY}

### **9. Special storage conditions**

Do not store above 30°C. Store tablets in strips in the provided carton to protect from light.

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\* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

**10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

**11. Name and address of the supplier**

S Kant Healthcare Ltd.  
3-A, Shiv Sagar Estate, North Wing,  
Dr. Annie Besant Road,  
Worli, Mumbai – 400018,  
India.

**12. WHO Reference Number (Prequalification Programme)**

TB413

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. (Advice on) General classification for supply**

Medicinal product subject to medical prescription.

**15. Instructions on use**

## MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP

Aluminium strips

**1. Name of the medicinal product**

[TB413 trade name]

Pyridoxine hydrochloride 10 mg tablets

**2. Name of the supplier**

S Kant Healthcare Ltd.

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**