

## **LABELLING**

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

Carton/ HDPE Bottle

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

[TB382 trade name]\*

Pyridoxine hydrochloride 10mg tablets

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

Each tablet contains 10 mg of pyridoxine hydrochloride.

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

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

Uncoated tablets

1x10 tablets

10x10 tablets

1x1000 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**

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**

Store in a dry place below 30°C, protected from light.

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

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

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

Macleods Pharmaceuticals Ltd.  
304, Atlanta Arcade,  
Marol Church Road,  
Andheri (East),  
Mumbai- 400 059,  
India

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

TB382

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

**14. General classification for supply**

Medicinal product subject to medical prescription

**15. Instructions on use**

## **MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP**

Blister/Strips

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

[TB382 trade name]

Pyridoxine hydrochloride 10mg tablets

### **2. Name of the supplier**

Macleods Pharmaceuticals Limited

### **3. India Expiry date**

EXP {MM/YYYY}

### **4. Manufacturer's batch number**

<Batch> <Lot>{number}

### **5. Other**