

## **LABELLING**

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

HDPE bottle

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

[TB403 trade name]\* Pretomanid 200 mg tablets  
Pretomanid

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

Each tablet contains 200 mg pretomanid

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

Contains lactose

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

Uncoated tablets  
26 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**

Store at a temperature below 30°C. Protect from moisture.

### **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**

Lupin Limited  
Kalpataru Inspire, 3<sup>rd</sup> Floor  
Off Western Express Highway

---

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

Santacruz (East)  
Mumbai – 400055  
India

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

TB403

**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**

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

Carton label

**1. Name of the medicinal product**

[TB403 trade name]<sup>†</sup> Pretomanid 200 mg tablets  
Pretomanid

**2. Statement of active substance**

Each tablet contains 200 mg pretomanid

**3. List of excipients**

Contains lactose

**4. Pharmaceutical form and contents**

Uncoated tablets

10 x 10 tablets

12 x 10 tablets

6 x 14 tablets

12 x 14 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**

Store at a temperature below 30°C. Protect from moisture.

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

---

<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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

Lupin Limited  
Kalpataru Inspire, 3<sup>rd</sup> Floor  
Off Western Express Highway  
Santacruz (East)  
Mumbai – 400055  
India

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

TB403

**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**

PVC/PVDC on aluminium

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

[TB403 trade name] Pretomanid 200 mg tablets

Pretomanid

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

Lupin Limited

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> <Lot> {number}

### **5. Other**