

## **LABELLING**

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

Plastic (HDPE) bottle

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

[TB396 trade name]\* Bedaquiline (as fumarate) 100 mg tablets

Bedaquiline

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

Each tablet contains 120.89 mg bedaquiline fumarate equivalent to 100 mg bedaquiline.

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

Contains lactose.

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

Tablets

24 tablets

188 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 in the original container or package to protect from light. Avoid excursions above 30°C.

### **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

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

Kalpataru Inspire  
3rd Floor, Off Western Express Highway  
Santacruz (East), Mumbai 400055  
India

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

TB396

**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**

Blister / strip pack carton

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

[TB396 trade name] Bedaquiline (as fumarate) 100 mg tablets

Bedaquiline

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

Each tablet contains 120.89 mg bedaquiline fumarate equivalent to 100 mg bedaquiline.

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

Contains lactose

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

Tablets

*Blisters*

08 x 12 tablets

11 x 12 tablets

04 x 14 tablets

*Strips*

10 x 10 tablets

04 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**

Do not store above 30°C. Store in the original container or package to protect from light. Avoid excursions above 30°C.

**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  
3rd Floor, Off Western Express Highway  
Santacruz (East), Mumbai 400055  
India

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

TB396

**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 blisters/strips

**1. Name of the medicinal product**

[TB396 trade name] Bedaquiline (as fumarate) 100 mg tablets

Bedaquiline

**2. Name of the supplier**

Lupin Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**