

## **LABELLING**

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

Outer carton

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

[TB205 trade name]\* Levofloxacin (as hemihydrate) 250 mg tablets  
Levofloxacin hemihydrate

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

Each film-coated tablet contains 250 mg levofloxacin hemihydrate

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

See patient information leaflet for further information

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

Film-coated tablets  
1 x 10 tablets

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

Oral use.  
Do not chew.  
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. Keep away from light and moisture.

### **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**

Cipla Ltd.,  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg,  
Lower Parel  
Mumbai - 400 013  
India

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

TB205

**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**

### **Bottle label**

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

[TB205 trade name]<sup>†</sup> Levofloxacin (as hemihydrate) 250 mg tablets  
Levofloxacin hemihydrate

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

Each film-coated tablet contains 250 mg levofloxacin hemihydrate

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

See patient information leaflet for further information

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

Film-coated tablets  
50 tablets

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

Oral use.  
Do not chew.  
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. Keep away from light and moisture.

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

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<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**

Cipla Ltd.,  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg,  
Lower Parel  
Mumbai - 400 013  
India

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

TB205

**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

### Blister

**1. Name of the medicinal product**

[TB205 trade name] Levofloxacin (as hemihydrate) 250 mg tablets  
Levofloxacin hemihydrate

**2. Name of the supplier**

Cipla Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot>{number}

**5. Other**