

## **LABELLING**

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

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

[TB227 trade name]<sup>1</sup> Levofloxacin (as hemihydrate) 500 mg tablets  
Levofloxacin (as hemihydrate)

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

Each film-coated tablet contains 500 mg of levofloxacin (as hemihydrate).

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

Contains FD&C Yellow#5 (tartrazine). See patient information leaflet for further information.

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

50 film-coated 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 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**

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

Cipla Ltd.,  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg,

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

Lower Parel  
Mumbai - 400 013  
India  
Tel. No.: 9122 28426000  
Fax No.: 9122 24826120  
e-mail: globalra@cipla.com

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

TB227

**13. Manufacturer's batch number**

<Batch> {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 LABEL**

**1. Name of the medicinal product**

[TB227 trade name]<sup>2</sup> Levofloxacin (as hemihydrate) 500 mg tablets  
Levofloxacin (as hemihydrate)

**2. Statement of active substance**

Each film-coated tablet contains 500 mg of levofloxacin (as hemihydrate).

**3. List of excipients**

Contains FD&C Yellow#5 (tartrazine). See patient information leaflet for further information.

**4. Pharmaceutical form and contents**

10 film-coated 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 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**

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

Cipla Ltd.,  
Cipla House  
Peninsula Business Park  
Ganpatrao Kadam Marg,

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<sup>2</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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Tel. No.: 9122 28426000  
Fax No.: 9122 24826120  
e-mail: globalra@cipla.com

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

TB227

**13. Manufacturer's batch number**

<Batch> {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**

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

[TB227 trade name]<sup>3</sup> Levofloxacin (as hemihydrate) 500 mg tablets

Levofloxacin (as hemihydrate)

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

Cipla Limited

### **3. Expiry date**

EXP {MM/YYYY}

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

<Batch> {number}

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<sup>3</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.