

## **LABELLING**

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

HDPE bottle

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

[TB238 trade name]\* levofloxacin 500 mg tablets

Levofloxacin

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

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

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

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

100 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 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 a dry place and protect from light.

### **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**

Micro Labs Limited

# 31, Race Course Road

Bengaluru 560 001,

Karnataka,

India.

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

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

TB238

**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 carton

**1. Name of the medicinal product**

[TB238 trade name]<sup>†</sup> levofloxacin 500 mg tablets  
Levofloxacin

**2. Statement of active substance**

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

**3. List of excipients**

**4. Pharmaceutical form and contents**

10 x 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 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 a dry place and protect from light.

**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**

Micro Labs Limited  
# 31, Race Course Road  
Bengaluru 560 001,  
Karnataka,  
India

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

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

TB238

**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-aluminium blister

**1. Name of the medicinal product**

[TB238 trade name] levofloxacin 500 mg tablets

Levofloxacin

**2. Name of the supplier**

Micro Labs Limited

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> <Lot> {number}

**5. Other**