

## **LABELLING**

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

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

[TB277 trade name]<sup>1</sup> Levofloxacin (as hemihydrate) 250 mg tablets  
Levofloxacin (as hemihydrate)

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

Each film-coated tablet contains 250 mg of levofloxacin (as hemihydrate).

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

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

5 x 20 film-coated tablets

9 x 10 film-coated tablets

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**

Store below 30°C, in dry place protected from light. Store tablets in the blisters in the provided carton.

### **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**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade,  
Marol Church road,

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

Andheri (East),  
Mumbai – 400 059, India.

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

TB277

**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**

[TB277 trade name]<sup>2</sup> Levofloxacin (as hemihydrate) 250 mg tablets  
Levofloxacin (as hemihydrate)

**2. Name of the supplier**

Macleods Pharmaceuticals Ltd

**3. Expiry date**

EXP {MM/YYYY}

**4. Manufacturer's batch number**

<Batch> {number}

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