

## **LABELLING**

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

Carton

**1. Name of the medicinal product**

[TB381 trade name]\* Levofloxacin (as hemihydrate) 250 mg tablets

Levofloxacin (as hemihydrate)

**2. Statement of active substance**

Each tablet contains 250 mg levofloxacin (as hemihydrate)

**3. List of excipients**

**4. Pharmaceutical form and contents**

Tablets.

1 x 10 tablets

10 x 10 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. Keep the tablets in the blister in the provided carton to protect 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**

Remington Pharmaceutical Industries (Pvt) Ltd

18km Multan Road,

Lahore 53800,

Pakistan

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

TB381

**13. Manufacturer's batch number**

<Batch> <Lot> {number}

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

**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**

### **Blisters**

- 1. Name of the medicinal product**  
[TB381 trade name] Levofloxacin (as hemihydrate) 250 mg tablets
- 2. Name of the supplier**  
Remington Pharmaceutical Industries (Pvt) Ltd
- 3. Expiry date**  
EXP {MM/YYYY}
- 4. Manufacturer's batch number**  
<Batch> <Lot>{number}
- 5. Other**