LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. **Name of the medicinal product**
   [TB381 trade name]* Levofloxacin (as hemihydrate) 250mg tablets

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}

14. **(Advice on) General classification for supply**
    Medicinal product subject to medical prescription.

---

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

15. Instructions on use

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) 250mg 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**