

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton

1. Name of the medicinal product

[TB381 trade name]* Levofloxacin 250 mg tablets

Levofloxacin

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

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

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 OR STRIP

Blisters

- 1. Name of the medicinal product**
[TB381 trade name] Levofloxacin 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**