LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
CARTON (Blister)

1.   **Name of the medicinal product**

[TB356 trade name]*

Levofloxacin (as hemihydrate) 100mg dispersible tablets

2.   **Statement of active substance**

Each dispersible tablet contains 100 mg of levofloxacin (as hemihydrate).

3.   **List of excipients**

4.   **Pharmaceutical form and contents**

10 Tablets (1 x 10 Tablets)
14 Tablets (1 x 14 Tablets)
100 Tablets (10 x 10 Tablets)
140 Tablets (10 x 14 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.

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,
Bangalore 560 001, Karnataka,
India

---

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

Manufactured by:
Micro Labs Limited
Unit-3
92, Sipcot Industrial Complex
Hosur – 635126
India.

12. WHO Reference Number (Prequalification Programme)

TB356

13. Manufacturer's batch number

<Batch> <Lot> {number}

14. General classification for supply

To be decided by the national medicines regulatory authority in accordance with national
legislation.

15. Instructions on use

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIP
PVC/PE/PVdC-Alu blister

1. Name of the medicinal product

[TB356 trade name]

Levofloxacin (as hemihydrate) 100mg dispersible tablets

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other