

LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
HDPE Bottle**

1. Name of the medicinal product

[TB355 trade name]*

Levofloxacin (as hemihydrate) 750 mg film-coated tablets

2. Statement of active substance

Each film coated tablet contains 750 mg of levofloxacin (as hemihydrate).

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablets

100 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. Store in the original pack.

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
Manufactured by:

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

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

12. WHO Reference Number (Prequalification Programme)

TB355

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Carton (PVC-ALU Blister)

1. Name of the medicinal product

[TB355 trade name][†]

Levofloxacin (as hemihydrate) 750 mg film-coated tablets

2. Statement of active substance

Each film coated tablet contains 750 mg of levofloxacin (as hemihydrate).

3. List of excipients

4. Pharmaceutical form and contents

Film-coated 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. Store in the original pack.

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)

TB355

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-ALU Blister**

1. Name of the medicinal product

[TB355 trade name]

Levofloxacin (as hemihydrate) 750 mg film-coated 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