

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB355 trade name]* Levofloxacin 750 mg tablets

Levofloxacin

2. Statement of active substance

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

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

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
Bengaluru – 560 001
Karnataka
India.

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

12. WHO Reference Number (Prequalification Programme)

TB355

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister carton

1. Name of the medicinal product

[TB355 trade name][†] Levofloxacin 750 mg tablets
Levofloxacin

2. Statement of active substance

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

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet
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 tablets in blisters in the provided carton.

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
Bengaluru– 560 001
Karnataka
India.

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

12. WHO Reference Number (Prequalification Programme)

TB355

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

PVC/Alu blisters

1. Name of the medicinal product

[TB355 trade name] Levofloxacin 750 mg tablets

Levofloxacin

2. Name of the supplier

Micro Labs Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> <Lot> {number}

5. Other