

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

HDPE Bottle

1. Name of the medicinal product

[TB338 trade name]* Levofloxacin 250 mg Film-coated Tablets

2. Statement of active substance

Each film coated tablets contains levofloxacin hemihydrate USP equivalent to levofloxacin 250 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated tablets

50 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}

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

9. Special storage conditions

Do not store above 30°C. 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

MSN Laboratories Private Limited
“MSN House”, Plot No. C-24
Industrial Estate, Sanath Nagar
Hyderabad, Telangana
500 018, India

12. WHO Reference Number (Prequalification Programme)

TB338

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
Carton (PVC/ALU BLISTERS)

1. Name of the medicinal product

[TB338 trade name][†] Levofloxacin 250 mg Film-coated Tablets

2. Statement of active substance

Each film coated tablets contains levofloxacin hemihydrate USP equivalent to levofloxacin 250 mg.

3. List of excipients

See patient information leaflet for further information.

4. Pharmaceutical form and contents

Film-coated 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}

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

9. Special storage conditions

Do not store above 30°C. 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

MSN Laboratories Private Limited
“MSN House”, Plot No. C-24
Industrial Estate, Sanath Nagar
Hyderabad, Telangana
500 018, India

12. WHO Reference Number (Prequalification Programme)

TB338

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

1. Name of the medicinal product

[TB338 trade name] Levofloxacin 250 film-coated Tablets

2. Name of the supplier

MSN Laboratories Private Limited

3. Expiry date

EXP {MM/YYYY}

4. Manufacturer's batch number

<Batch> {number}

5. Other