

LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE bottle

1. Name of the medicinal product

[TB338 trade name]* Levofloxacin 250 mg tablets

Levofloxacin

2. Statement of active substance

Each film coated tablets contains levofloxacin 250 mg (as hemihydrate)

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

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}

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

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

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

Blister pack carton

1. Name of the medicinal product

[TB338 trade name][†] Levofloxacin 250 mg tablets

Levofloxacin

2. Statement of active substance

Each film coated tablets contains levofloxacin 250 mg (as hemihydrate)

3. List of excipients

4. Pharmaceutical form and contents

Film-coated tablet

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. 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

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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

PVC/Alu blisters

1. Name of the medicinal product

[TB338 trade name] Levofloxacin 250 mg tablets

Levofloxacin

2. Name of the supplier

MSN Laboratories Private Limited

3. Expiry date

4. Manufacturer's batch number

<Batch> <Lot>{number}

5. Other