

## **LABELLING**

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

### **HDPE Bottle**

#### **1. Name of the medicinal product**

[TB339 trade name]\* Levofloxacin 500 mg Film-coated Tablets

#### **2. Statement of active substance**

Each film coated tablets contains levofloxacin hemihydrate USP equivalent to levofloxacin 500 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}

#### **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**

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

**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)**

TB339

**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**

[TB339 trade name]<sup>†</sup> Levofloxacin 500 mg Film-coated Tablets

#### **2. Statement of active substance**

Each film coated tablets contains levofloxacin hemihydrate USP equivalent to levofloxacin 500 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}

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<sup>†</sup> 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)**

TB339

**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**

[TB339 trade name] Levofloxacin 500 mg 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**