

## **LABELLING**

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

HDPE bottle label

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

[TB341 trade name]\* Moxifloaxacin (as hydrochloride) 400 mg tablets

Moxifloxacin (as hydrochloride)

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

Each tablet contains moxifloxacin hydrochloride Ph. Eur. equivalent to 400mg moxifloxacin.

### **3. List of excipients**

Contains lactose

See patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

Film-coated tablets

30 tablets

500 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

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

Hyderabad  
Telangana– 500 018  
India

**12. WHO Reference Number (Prequalification Programme)**

TB341

**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 label

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

[TB341 trade name]<sup>†</sup> Moxifloaxacin (as hydrochloride) 400 mg tablets

Moxifloxacin (as hydrochloride)

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

Each tablet contains moxifloxacin hydrochloride Ph. Eur. equivalent to 400mg moxifloxacin.

### **3. List of excipients**

Contains lactose

See patient information leaflet for further information.

### **4. Pharmaceutical form and contents**

Film-coated tablets

3 x 5 tablets

5 x 7 tablets

3 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

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

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**12. WHO Reference Number (Prequalification Programme)**

TB341

**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/PVDC on aluminium foil blisters

**1. Name of the medicinal product**

[TB341 trade name] Moxifloxacin (as hydrochloride) 400 mg tablets

Moxifloxacin (as hydrochloride)

**2. Name of the supplier**

MSN Laboratories Private Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot> number

**5. Other**