

## **LABELLING**

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

HDPE bottle label

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

[TB286 trade name]\* Moxifloxacin (as hydrochloride) 400 mg tablets

Moxifloxacin (as hydrochloride)

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

Each film-coated tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin

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

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

Film-coated tablets

100 film-coated 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 package.

### **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**

Mylan Laboratories Limited  
Plot No. 564/A/22  
Road No.92, Jubilee Hills  
Hyderabad - 500096,  
Telangana,  
India

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

Email: ProductSafety@viatris.com

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

TB286

**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 label

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

[TB286 trade name]<sup>†</sup> Moxifloxacin (as hydrochloride) 400 mg tablets

Moxifloxacin (as hydrochloride)

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

Each film-coated tablet contains moxifloxacin hydrochloride equivalent to 400 mg moxifloxacin

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

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

Film-coated tablets

1 x 10 film-coated tablets

10 x 10 film-coated 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 package.

### **10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate**

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**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 blister

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Moxifloxacin (as hydrochloride)

**2. Name of the supplier**

Mylan Laboratories Limited

**3. Expiry date**

**4. Manufacturer's batch number**

<Batch> <Lot> number

**5. Other**