

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**OUTER PACKING**

**1. NAME OF THE MEDICINAL PRODUCT**

[Product name] 5mg/ml eye drops, solution  
Moxifloxacin

**2. STATEMENT OF ACTIVE SUBSTANCE**

1 ml of solution contains 5 mg of Moxifloxacin (as hydrochloride).

**3. LIST OF EXCIPIENTS**

Excipients: boric acid, sodium chloride, sodium hydroxide for pH adjustment and water for injection.

See the package leaflet for further details.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Eye drops solution  
1 x 5 ml

**5. METHOD AND ROUTE OF ADMINISTRATION**

Ocular use. Read the package leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Remove contact lenses before use.

**8. EXPIRY DATE**

EXP  
Discard four weeks after first opening  
Opened:

**9. SPECIAL STORAGE CONDITIONS**

**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 MARKETING AUTHORISATION HOLDER**

<[To be completed nationally]>

**12. MARKETING AUTHORISATION NUMBER(S)**

<[To be completed nationally]>

**13. BATCH NUMBER**

Lot

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

<[To be completed nationally]>

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included.

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC: {number}

SN: {number}

NN: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Bottle**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION**

[Product name] 5mg/ml eye drops, solution  
Moxifloxacin  
Ocular use

**2. METHOD OF ADMINISTRATION**

Read the package leaflet before use.

**3. EXPIRY DATE**

EXP:  
Discard 4 weeks after first opening.  
Opened:

**4. BATCH NUMBER**

Lot:

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

5 ml

**6. OTHER**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS  
OVERWRAP**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION**

[Product name] 5mg/ml eye drops, solution  
Moxifloxacin

**2. METHOD OF ADMINISTRATION**

Read the package leaflet before use.

**3. EXPIRY DATE**

Exp:  
Discard 4 weeks after first opening

**4. BATCH NUMBER**

Lot:

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

5 ml

**6. OTHER**