

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER PACKING

1. NAME OF THE MEDICINAL PRODUCT

Moxifloxacin 5mg/ml eye drops, solution
Moxifloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

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
1x 5ml

5. METHOD AND ROUTE(S) 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 reach and sight 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)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Moxifloxacin 5mg/ml eye drops, solution

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(S) OF ADMINISTRATION

Moxifloxacin 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

5ml

6. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS OVERWRAP

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION

Moxifloxacin 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