

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING
{ CARTON }**

1. NAME OF THE MEDICINAL PRODUCT

Product name 5 mg/ml eye drops solution
Levofloxacin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One bottle of Product name 5 mg/ml eye drops solution contains 5 ml solution with levofloxacin as the active ingredient.
One ml of eye drops, solution, contains 5.12 mg levofloxacin hemihydrate equivalent to 5.0 mg of levofloxacin.
For the theoretical volume of one drop equivalent to 0.05ml the amount of drug substance is 0.256mg levofloxacin hemihydrate equivalent to 0.250 mg of levofloxacin

3. LIST OF EXCIPIENTS

Benzalkonium chloride, sodium chloride, sodium hydroxide solution or hydrochloric acid, Water for Injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Eye Drops Solution

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

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

No special requirements.
Keep out of reach and sight of children.

7. OTHER SPECIAL WARNINGS, IF NECESSARY

None

8. EXPIRY DATE

Exp

9. SPECIAL STORAGE CONDITIONS

Product name 5 mg/ml eye drops solution are to be used within 28 days after first opening the bottle.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS IF APPROPRIATE

None.

11. NAME AND ADDRESS OF MARKETING AUTHORISATION HOLDER

[To be completed nationally]

12. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Subject to medical prescription

15. INSTRUCTIONS FOR USE

16. INFORMATION TO APPEAR IN BRAILLE

Product name