

## **LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGING**

**CARTON**

**1. NAME OF THE MEDICINAL PRODUCT**

[Invented name] 50 micrograms/mL eye drops, solution  
Latanoprost

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each mL of solution contains 50 micrograms latanoprost.

**3. LIST OF EXCIPIENTS**

Excipients: Macrogolglycerol hydroxystearate 40, sodium chloride, disodium edetate, sodium dihydrogen phosphate dihydrate, anhydrous disodium phosphate, hydrochloric acid or/and sodium hydroxide (for pH adjustment), water for injections

**4. PHARMACEUTICAL FORM AND CONTENTS**

Eye drops, solution.

[X] number of bottles x 2.5 mL

**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 SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

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

Does not contain any preservatives.

**8. EXPIRY DATE**

EXP  
Discard 4 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**

<[To be completed nationally]>

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

[Invented name] 50 micrograms/mL

**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**

[Invented name] 50 micrograms/mL eye drops, solution  
Latanoprost  
Ocular use.

**2. METHOD OF ADMINISTRATION**

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Lot

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

2.5 mL

**6. OTHER**