

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER PACKING

1. NAME OF THE MEDICINAL PRODUCT

[PRODUCT NAME] Preservative-free 40 micrograms/mL eye drops solution, multi dose container
Travoprost

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml of solution contains 40 micrograms of travoprost.

3. LIST OF EXCIPIENTS

Excipients: Macrogolglycerol hydroxystearate 40, Boric acid, mannitol, sodium chloride, propylene glycol, sodium hydroxide (for pH-adjustment), purified water

See the leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Eye drops solution
1 x 2.5 ml
3 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

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

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[PRODUCT NAME] Preservative-free 40 micrograms/mL eye drops solution

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE/BOTTLE OVERWRAP

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

[PRODUCT NAME] Preservative-free 40 micrograms/mL eye drops solution, multi dose container
Travoprost
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

2.5 ml

6. OTHER