

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

[Invented name] 0.3 mg/mL + 5 mg/mL eye drops, solution
bimatoprost/timolol

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One mL of solution contains 0.3 mg of bimatoprost and 5 mg of timolol (as 6.8 mg of timolol maleate).

3. LIST OF EXCIPIENTS

Excipients: Sodium chloride, disodium hydrogen phosphate heptahydrate, citric acid monohydrate, sodium hydroxide or/and hydrochloric acid (for pH adjustment) and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Eye drops, solution.

1 x 3 mL
3 x 3 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

Remove contact lenses before use.
Does not contain any preservatives.

8. EXPIRY DATE

EXP:

Discard 4 weeks after first opening.

Opened:

Opened (1):

Opened (2):

Opened (3):

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] 0.3 mg/mL + 5 mg/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] 0.3 mg/mL + 5 mg/mL eye drops, solution
bimatoprost/timolol
Ocular use

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

3 mL

6. OTHER