

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**FOLDING BOX****LAST REVISED: 10/2020****1. NAME OF THE MEDICINAL PRODUCT**

<product name> 1.315 mg/ml eye drops single-dose container

dexamethasone sodium phosphate

2. STATEMENT OF ACTIVE SUBSTANCE

1 ml solution contains 1.315 mg dexamethasone sodium phosphate equivalent to 1 mg dexamethasone.

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, disodium phosphate anhydrous, sodium dihydrogen phosphate dihydrate, disodium edetate, water for injections.

Contains phosphates. Read the package leaflet.

4. PHARMACEUTICAL FORM AND CONTENTS

eye drops, solution
single-dose container à 0.4 ml

10 x 0.4 ml

20 x 0.4 ml

30 x 0.4 ml

50 x 0.4 ml

5. METHOD AND ROUTE OF ADMINISTRATION

Ocular use. Read the package leaflet.

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 WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP:

After opening the pouches, use within 6 months.

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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

<[to be completed nationally]>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

<[to be completed nationally]>

15. INSTRUCTIONS ON USE

Use eye drops immediately after opening.
Single-dose containers are intended for single use only. Discard any unused product.

16. INFORMATION IN BRAILLE

<[to be completed nationally]>

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

<[product code:] {number}>

<[serial number:] {number}>

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**FOIL POUCH****LAST REVISED: 10/2020****1. NAME OF THE MEDICINAL PRODUCT**

<product name> 1.315 mg/ml eye drops single-dose container

dexamethasone sodium phosphate

2. STATEMENT OF ACTIVE SUBSTANCE

1 ml solution contains 1.315 mg dexamethasone sodium phosphate equivalent to 1 mg dexamethasone.

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, disodium phosphate anhydrous, sodium dihydrogen phosphate dihydrate, disodium edetate, water for injections.

Contains phosphates. Read the package leaflet.

4. PHARMACEUTICAL FORM AND CONTENTS

eye drops, solution

5 single-dose containers à 0.4 ml

5. METHOD AND ROUTE OF ADMINISTRATION

Ocular use. Read the package leaflet.

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 WARNINGS, IF NECESSARY**8. EXPIRY DATE**

EXP:

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.

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

<[to be completed nationally]>

13. BATCH NUMBER

Lot:

14. GENERAL CLASSIFICATION FOR SUPPLY

<[to be completed nationally]>

15. INSTRUCTIONS ON USE

Use eye drops immediately after opening.
Single-dose containers are intended for single use only. Discard any unused product.

16. INFORMATION IN BRAILLE