PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Dexamethasone phosphate/DEMO 4 mg/mL Solution for injection

dexamethasone phosphate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 1 mL of solution for injection contains 3.32 mg of dexamethasone (as dexamethasone sodium phosphate) which is equivalent to 4.00 mg of dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate.

Each 2 mL of solution for injection contains 6.64 mg of dexamethasone (as dexamethasone sodium phosphate) which is equivalent to 8.00 mg of dexamethasone phosphate or 8.74 mg dexamethasone sodium phosphate.

Each 5 mL of solution for injection contains 16.6 mg of dexamethasone (as dexamethasone sodium phosphate) which is equivalent to 20.00 mg of dexamethasone phosphate or 21.85 mg dexamethasone sodium phosphate.

3. LIST OF EXCIPIENTS

Excipients: disodium edetate, propylene glycol (E1520), water for injections, and sodium hydroxide.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection

1 ampoule x 1 mL
5 ampoules x 1 mL
10 ampoules x 1 mL
20 ampoules x 1 mL
50 ampoules x 1 mL
100 ampoules x 1 mL

1 ampoule x 2 mL
5 ampoules x 2 mL
10 ampoules x 2 mL
20 ampoules x 2 mL
50 amploules x 2 mL
100 ampoules x 2 mL

1 ampoule x 5 mL
5 ampoules x 5 mL
10 ampoules x 5 mL
20 ampoules x 5 mL
50 ampoules x 5 mL
100 ampoules x 5 mL

4 mg/1 mL
8 mg/2 mL
20 mg/5 mL

GREEK MEDICINE [Logo]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

IV, IM, SC, intraarticular or intralesional 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:

9. SPECIAL STORAGE CONDITIONS

Store below 25 °C. Do not refrigerate or freeze. Keep the ampoules in the outer carton 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

Any unused portion of the product should be discarded immediately after use.

11.NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder and Manufacturer:
DEMO S.A. PHARMACEUTICAL INDUSTRY
21st Km National Road Athens–Lamia,
145 68 Krioneri, Attiki, Greece,
T: +30 210 8161802, F: +30 2108161587

12.MARKETING AUTHORISATION NUMBER(S)

Reg. No.:

13.BATCH NUMBER

Lot:

14.GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15.INSTRUCTIONS ON USE

16.INFORMATION IN BRAILLE

Not applicable. For hospital use only.

17.UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18.UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

AMPOULE

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

Dexamethasone phosphate/DEMO 4 mg/mL Solution for injection

dexamethasone phosphate

IV, IM, SC, intraarticular, intralesional use

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

LOT:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

4 mg / 1 mL
8 mg / 2 mL
20 mg / 5 mL

6. OTHER

Marketing Authorisation Holder and Manufacturer: DEMO S.A. [Logo]