

## **LABELLING**

### **PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

#### **OUTER CARTON**

#### **1. NAME OF THE MEDICINAL PRODUCT**

Dexamethasone 3.3 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.

#### **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

**4 mg / 1 mL**

#### **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:** Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus

**Manufacturer:** DEMO S.A. PHARMACEUTICAL INDUSTRY, 21<sup>st</sup> km National Road Athens-Lamia, 145 68 Krioneri, Attiki, Greece. T: +30 210 8161802, F: +30 210 8161587

**12. MARKETING AUTHORISATION NUMBER(S)**

PL 24598/0075

**13. BATCH NUMBER**

Lot:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

POM

**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 3.3 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**

1 mL

**6. OTHER**

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