

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

**Carton box 3 x 1-ml ampoules**

**1. NAME OF THE MEDICINAL PRODUCT**

Dexamethasone KERN PHARMA 4 mg/ml solution for injection Generic Medicinal Product

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each 1-ml ampoule contains 4 mg dexamethasone (as dexamethasone phosphate)

**3. LIST OF EXCIPIENTS**

Excipients: methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium edetate, sodium citrate, sodium hydroxide and water for injection.

For more information please refer to the package leaflet

**4. PHARMACEUTICAL FORM AND CONTENTS**

3 x 1-ml ampoules

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use  
Intravenous use  
Intraarticular use  
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 in the original package in order to protect from light  
Do not freeze

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**



Sigre<sup>1</sup> logotype: [Logotype illegible: ]

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Kern Pharma S.L.**  
Polígono Ind. Colón II. Venus, 72  
08228 Terrassa (Barcelona)

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

**13. BATCH NUMBER**

Batch

**14. GENERAL CLASSIFICATION FOR SUPPLY**

**MEDICINAL PRODUCT SUBJECT TO MEDICAL PRESCRIPTION**

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Dexamethasone 4 mg/ml sol. for inj.

**17. OTHER INFORMATION**

National Code  
Symbols and acronyms: [Symbol illegible: O]  
Cut-out coupon<sup>2</sup>:  
Spanish Social Security Medical Assistance<sup>3</sup>  
Kern Pharma S.L.  
Dexamethasone KERN PHARMA 4 mg/ml solution for injection Generic Medicinal Product

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

**CLINICAL PACK**

**1. NAME OF THE MEDICINAL PRODUCT**

Dexamethasone KERN PHARMA 4 mg/ml solution for injection Generic Medicinal Product

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

<sup>1</sup> [Translator's Note: Sigre refers to containers belonging to the Spanish *Sistema Integrado de Gestión y Recogida de Envases* (Integrated Packaging Collection and Management System)].

<sup>2</sup> [Translator's Note: *Cupón precinto* refers in Spanish to a cut-out coupon on boxes of medications that contains the details for the Spanish Social Security system regarding reimbursement. The chemist tears it out along the perforated edges and then sellotapes it to the prescription, to prove that the discounted amount has been charged for the correct drug].

<sup>3</sup> [Translator's Note: A.S.S.S. stands for *Asistencia Sanitaria de la Seguridad Social*].

Each 1-ml ampoule contains: 4 mg dexamethasone (as dexamethasone phosphate)

**3. LIST OF EXCIPIENTS**

Excipients: methyl parahydroxybenzoate, propyl parahydroxybenzoate, disodium edetate, sodium citrate, sodium hydroxide and water for injection.

For more information please refer to the package leaflet

**4. PHARMACEUTICAL FORM AND CONTENTS**

100 x 1-ml ampoules

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use  
Intravenous use  
Intraarticular use  
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**

Clinical pack. Not for retail sale.

**8. EXPIRY DATE**

EXP.

**9. SPECIAL STORAGE CONDITIONS**

Store in the original package in order to protect from light  
Do not freeze

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

*Sigre*<sup>4</sup> logotype: [Logotype illegible: ]

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Kern Pharma S.L.**  
Polígono Ind. Colón II. Venus, 72  
08228 Terrassa (Barcelona)

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

<sup>4</sup> [Translator's Note: *Sigre* refers to containers belonging to the Spanish *Sistema Integrado de Gestión y Recogida de Envases* (Integrated Packaging Collection and Management System)].

**13. BATCH NUMBER**

Batch

**14. GENERAL CLASSIFICATION FOR SUPPLY**

**MEDICINAL PRODUCT SUBJECT TO MEDICAL PRESCRIPTION**

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

Dexamethasone 4 mg/ml sol. for inj

**17. OTHER INFORMATION**

Pharmaceutical company code 863, KERN PHARMA, S.L.  
CLINICAL PACK  
National Code  
Symbols and acronyms: [Symbol illegible: ○]  
Cut-out coupon<sup>5</sup> for clinical packs

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1-ml ampoule**

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

Dexamethasone KERN PHARMA 4 mg/ml

**2. METHOD OF ADMINISTRATION**

Intramuscular use  
Intravenous use  
Intraarticular use  
Intralesional use

**3. EXPIRY DATE**

EXP

**4. BATCH NUMBER**

Batch

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

1 ml

<sup>5</sup> [Translator's Note: *Cupón precinto* refers in Spanish to a cut-out coupon on boxes of medications that contains the details for the Spanish Social Security system regarding reimbursement. The chemist tears it out along the perforated edges and then sellotapes it to the prescription, to prove that the discounted amount has been charged for the correct drug].

<b>6. OTHER</b>
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Kern Pharma logotype