

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Box with vial(s) of 100 ml/250 ml

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

DINALGEN 60 mg/ml solution for injection for pigs (all countries except DK, SE and FI)

DINALGEN (DK)

DINALGEN VET (SE and FI)

Ketoprofen

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

Ketoprofen	60 mg
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Benzyl alcohol (E1519)	10 mg
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**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml

250 ml

10 x100 ml

10x250 ml

**5. TARGET SPECIES**

Pigs.

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Meat and offal: 3 days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf-life after first broaching the immediate packaging: 28 days

Once broached, use by:...

**11. SPECIAL STORAGE CONDITIONS**

This veterinary medicinal product does not require any special storage conditions.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

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

ECUPHAR VETERINARIA, S.L.U.  
C/Cerdanya, 10-12 Planta 6º  
08173 Sant Cugat del Vallés  
Barcelona (Spain)

**16. MARKETING AUTHORISATION NUMBER(S)****17. MANUFACTURER’S BATCH NUMBER**

<Batch> <Lot> <BN> {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Vials containing 100 ml/250 ml

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

DINALGEN 60 mg/ml solution for injection for pigs (all countries except DK, SE and FI)

DINALGEN (DK)

DINALGEN VET (SE and FI)

Ketoprofen

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains: Ketoprofen 60 mg, Benzyl alcohol (E1519) 10 mg

**3. PHARMACEUTICAL FORM****4. PACKAGE SIZE**

100 ml

250 ml

**5. TARGET SPECIES**

Pigs.

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use

**8. WITHDRAWAL PERIOD**

Meat and offal: 3 days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf-life after first opening the immediate packaging: 28 days

Once broached, use by .....

<b>11. SPECIAL STORAGE CONDITIONS</b>
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<b>12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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<b>10 13.THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE</b>
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For animal treatment only.To be supplied only on veterinary prescription.

<b>14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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<b>15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</b>
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ECUPHAR VETERINARIA, S.L.U.  
C/Cerdanya, 10-12 Planta 6º  
08173 Sant Cugat del Vallés  
Barcelona (Spain)

<b>16. MARKETING AUTHORISATION NUMBER(S)</b>
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<b>17. MANUFACTURER’S BATCH NUMBER</b>
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<Batch> <Lot> <BN> {number}

