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 Benzyl alcohol (E1519) 10 mg

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 <u>broaching</u> 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 6° 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

11. SPECIAL STORAGE CONDITIONS

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

10 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"
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