

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DINALGEN 150 mg/ml solution for injection for cattle, pigs and horses (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 150 mg

Benzyl alcohol (E1519) 10 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 100 ml

5 x 100 ml

10 x 100 ml

1 x 250 ml

5 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

Meat and offal: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in mares producing milk for human consumption

Pigs:

Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental self injection. Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

Shelf-life after opening the container for the first time: 28 days.

Once broached, use by: ...

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

12. SPECIAL 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

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 150 mg/ml solution for injection for cattle, pigs and horses (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 150 mg

Benzyl alcohol (E1519) 10 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:

Meat and offal: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in mares producing milk for human consumption

Pigs:

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

Keep the vial in the outer carton.

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

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

17. MANUFACTURER’S BATCH NUMBER

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

