

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

100 ml  
500 ml

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

DANIDOL 300 mg/ml Oral Solution for Cattle and Pigs (AT, DE, FR, UK)  
EDERAL 300 mg/ml Oral Solution for Cattle and Pigs (only ES)

Ketoprofen

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

Each ml contains 300 mg of Ketoprofen.

**3. PHARMACEUTICAL FORM**

Oral solution.

**4. PACKAGE SIZE**

100 ml.  
500 ml.

**5. TARGET SPECIES**

Fattening Cattle and Pigs.

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

Oral use, administer in drinking water.

**8. WITHDRAWAL PERIOD**

Meat and offal: 1 day

**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: 3 months  
Once opened, used by....  
Shelf life after reconstitution in drinking water: 24 hours

<b>11. SPECIAL STORAGE CONDITIONS</b>
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Keep the bottle tightly closed.

<b>12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

<b>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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Keep out of the sight and reach of children.

<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}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

100 ml  
500 ml

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

DANIDOL 300 mg/ml Oral Solution for Cattle and Pigs (AT, DE, FR, UK)  
EDERAL 300 mg/ml Oral Solution for Cattle and Pigs (only ES)

Ketoprofen

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

Each ml contains 300 mg of Ketoprofen

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

100 ml.  
500 ml.

**5. TARGET SPECIES**

Fattening Cattle and Pigs.

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

Oral use, administer in drinking water.

**8. WITHDRAWAL PERIOD**

Meat and offal: 1 day

**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: 3 months  
Once opened, use by: ...  
Shelf life after reconstitution in drinking water: 24 hours

<b>11. SPECIAL STORAGE CONDITIONS</b>
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Keep the bottle tightly closed.

<b>12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY</b>
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<b>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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<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}

