

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

Labels for 100 ml and 250 ml vials

Individual boxes for 50 ml, 100 ml and 250 ml vials

Boxes with 10 vials of 50 ml, 100 ml or 250 ml

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION for horses, cattle and pigs

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 50 ml

1 x 100 ml

1 x 250 ml

10 x 50 ml

10 x 100 ml

10 x 250 ml

5. TARGET SPECIES

Horses, cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses: Meat and offal: 4 days.

Milk: zero hours.

Cattle: Meat and offal: 4 days

Milk: zero hours

Pigs: Meat and offal: 4 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 28 days

Once opened, use by....

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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

CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)
Tel: 34 977 / 757 273

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for 50 ml vials

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION for horses, cattle and pigs
Ketoprofen

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

100 mg/ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml.

4. ROUTE(S) OF ADMINISTRATION

Intramuscular (cattle and pigs) or intravenous (horses and cattle).

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses: Meat and offal: 4 days.

Milk: zero hours.

Cattle: Meat and offal: 4 days

Milk: zero hours

Pigs: Meat and offal: 4 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use within 28 days.

Once opened, use by....

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.