

A. LABELLING



PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with vial(s) of 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 150 mg

3. PACKAGE SIZE

1 x 50 ml

1 x 100 ml

1 x 250 ml

12 x 50 ml

10 x 100 ml

10 x 250 ml

4. TARGET SPECIES

Cattle, pigs and horses



5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

7. WITHDRAWAL PERIODS

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

Pig:

Meat and offal: 3 days



8. EXPIRY DATE
Exp. {mm/yyyy}
Once opened use within 28 days. Use by:
9. SPECIAL STORAGE PRECAUTIONS
Keep the vial in the outer carton in order to protect from light.
10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"
Read the package leaflet before use.
11. THE WORDS "FOR ANIMAL TREATMENT ONLY"
For animal treatment only.
12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"
Keep out of the sight and reach of children.
13. NAME OF THE MARKETING AUTHORISATION HOLDER
Labiana Life Sciences, S.A.
14. MARKETING AUTHORISATION NUMBERS
xxxxxx

15. BATCH NUMBER

Lot: {number}

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PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 150 mg

3. TARGET SPECIES

Cattle, pigs and horses



4. ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.

5. WITHDRAWAL PERIODS

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

Pig:

Meat and offal: 3 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Use by:

7. SPECIAL STORAGE PRECAUTIONS



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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

9. BATCH NUMBER

Lot: {number}



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 150 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

Use by: