

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**Vial (label for a 100 or 250 ml)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NIGLUMINE 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Flunixin50.0 mg
(equivalent to 82.9 mg flunixin meglumine)

3. TARGET SPECIES

Cattle, horses, pigs.

4. ROUTES OF ADMINISTRATION

Cattle: intravenous use.

Horse: intravenous use.

Pig: intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 4 days (intravenous use)

Milk: 24 hours (intravenous use).

Pigs:

Meat and offal: 28 days (intramuscular use).

Horses:

Meat and offal: 5 days (intravenous use).

Milk: Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

Use by ...

7. SPECIAL STORAGE CONDITIONS**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

LABORATORIOS CALIER, S.A.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (label for 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NIGLUMINE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Flunixin 50.0 mg
(equivalent to 82.9 mg flunixin meglumine)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached: use within 28 days.

Used by...

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**Cardboard box****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NIGLUMINE 50 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Flunixin..... 50.0 mg
(equivalent to 82.9 mg flunixin meglumine)

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, horses, pigs

5. INDICATION(S)**6. ROUTES OF ADMINISTRATION**

Cattle: intravenous use.
Horse: intravenous use.
Pig: intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 4 days (intravenous days).

Milk: 24 hours (intravenous use).

Pigs:

Meat and offal: 28 days (intramuscular use).

Horses:

Meat and offal: 5 days (intravenous use).

Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Used by ...

9. SPECIAL STORAGE CONDITIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
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Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
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For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”
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Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBER(S)
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15. BATCH NUMBER

Lot {number}

