

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL ON VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NIGLUMINE 50 mg/ml solution for injection for cattle, horses and pigs
Flunixin meglumine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Flunixin (meglumine)..... 50.0 mg
(Equivalent to 82.9 mg flunixin meglumine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, horses and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 4 days. Milk: 24 hours
Horses: Meat and offal: 28 days
Pigs: Meat and offal 28 days
Not permitted for use in lactating horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the immediate packaging: 28 days.
Once broached, use by ...

11. SPECIAL STORAGE CONDITIONS

None

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

Any unused veterinary medicinal product or waste material 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

Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

**<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
(CARDBOARD CARTON)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NIGLUMINE 50 mg/ml solution for injection for cattle, horses and pigs
Flunixin meglumine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance

Flunixin (meglumine) 50.0 mg

(Equivalent to 82.9 mg flunixin meglumine)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

100 ml

250 ml

5. TARGET SPECIES

Cattle, horses and pigs

6. INDICATION(S)

Cattle: For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs.

Horses: For the alleviation of inflammation and pain associated with musculoskeletal disorders, especially in acute to sub-acute stages and to relieve visceral pain associated with colic.

Pigs: For alleviation of Mastitis-Metritis-Agalactia Syndrome (MMA) with appropriate antibiotic treatment to reduce clinical signs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 4days Milk: 24 hours

Horses: Meat and offal: 28 days

Pigs: Meat and offal 28 days

Not permitted for use in lactating horses producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf-life after first opening of the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions

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

Any unused veterinary medicinal product or waste material 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

Laboratorios Calier, S.A.

Barcelonès, 26 (Pla del Ramassà)

Les Franqueses del Vallès (Barcelona)

SPAIN

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}