

**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}