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

- Flunixin meglumine

Authorised

Product identification

Medicine name:
NIGLUMINE 50mg/ml solution for injection for cattle, horses and pigs
Active substance:

- Flunixin meglumine

Target species:

- Cattle
- Horse
- Pig

Route of administration:

- Intravenous use
- Intramuscular use

Product details

Active substance and strength:

- Flunixin meglumine
  5.00
  gram(s)
  /
  100.00
  millilitre(s)

Pharmaceutical form:

- Solution for injection

Withdrawal period by route of administration:

- Intravenous use
  - Cattle
    - Meat and offal
      4
      day

        - Milk
          24
          hour
        - Meat and offal
          4
          day
        - Milk
          24
          hour
    - Horse
        - Meat and offal
          28
          day
    - Cattle
        - Meat and offal
          4
          day
        - Milk
          24
          hour
        - Meat and offal
          4
          day
        - Milk
          24
          hour
- Intramuscular use
    - Pig
        - Meat and offal
          28
          day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

- QM01AG90

Legal status of supply:

- Veterinary medicinal product subject to veterinary prescription

Authorisation status:

- Valid

Authorised in:

- Germany

Available in:

- Germany

Package description:

- box containing 1 vial of 50 ml
- box containing 1 vial of 250 ml
- box containing 1 vial of 100 ml

Additional information

Entitlement type:

- Marketing Authorisation

Legal basis of product authorisation:

- Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

- Laboratorios Calier S.A.

Marketing authorisation date:

- 4/07/2008

Manufacturing sites for batch release:

- Laboratorios Calier S.A.

Responsible authority:

- Federal Office Of Consumer Protection And Food Safety

Authorisation number:

- 401141.00.00

Date of authorisation status change:

- 21/05/2012

Reference member state:

- Spain

Procedure number:

- ES/V/0127/001

Concerned member states:

- Austria

- Belgium
- Bulgaria
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Portugal
- Romania

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Product information

Labelling

English (PDF)
Published on: 30/10/2025
Updated on: 13/03/2026
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Combined File of all Documents

English (PDF)
Published on: 13/03/2026
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Other languages (1)
German (PDF)
Published on: 13/03/2026
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Summary of Product Characteristics

English (PDF)
Published on: 30/10/2025
Updated on: 13/03/2026
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Package Leaflet

English (PDF)
Published on: 30/10/2025
Updated on: 13/03/2026
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