FLORFENIS 300 mg/ml solution for injection for cattle, sheep and pigs

Authorised

- Florfenicol

Product identification

Medicine name:
FLORFENIS 300 mg/ml solution for injection for cattle, sheep and pigs

Active substance:
Florfenicol

Target species:
Cattle
Pig
Sheep

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Florfenicol

300.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 30 day
  - Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

- **Pig**
  - Meat and offal. 18 day

- **Sheep**
  - Meat and offal. 39 day
  - Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

- **Cattle**
  - Meat and offal. 30 day
  - Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

- **Sheep**
  - Meat and offal. 39 day

- Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Subcutaneous use:

- **Cattle**
  - Meat and offal. 44 day
  - Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

- **Cattle**
  - Meat and offal. 44 day
  - Milk. no withdrawal period

Milk: Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01BA90

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Spain

Available in:
Spain

Package description:
box containing 6 vials of 250 ml

box containing 6 vials of 100 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 Syva S.A.

Marketing authorisation date:
19/02/2021

Manufacturing sites for batch release:
Laboratorios Syva S.A.

Responsible authority:
Spanish Agency Of Medicines And Medical Devices

Authorisation number:
3972 ESP

Date of authorisation status change:
22/09/2021

Reference member state:
Spain

Procedure number:
ES/V/0377/001

Concerned member states:
Belgium Denmark France Germany Greece Hungary Ireland Italy Lithuania Netherlands Poland Portugal Romania

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

Documents

Combined File of all Documents

Summary of Product Characteristics

English (PDF)
Published on: 27/06/2024
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Package Leaflet

English (PDF)
Published on: 27/06/2024
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Labelling

English (PDF)
Published on: 27/06/2024
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