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
FLORFENIS 300 mg/ml solutie injectabila pentru bovine, ovine si porcine

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. no withdrawal period

Meat and offal: Intramuscular use (20 mg / kg bw, twice): 30 days / Subcutaneous use (40 mg / kg bw, once): 44 days

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

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

- **Cattle**
  - 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**
  - 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. no withdrawal period

Meat and offal: Intramuscular use (20 mg / kg bw, twice): 30 days / Subcutaneous use (40 mg / kg bw, once): 44 days

- **Cattle**
  - 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:
Romania

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:
10/05/2021

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

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
210059

Date of authorisation status change:
26/05/2024

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

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

Package Leaflet

Labelling

eu-PUAR-florfenis-300-mg-ml-solution-for-injection-for-cattle--sheep-and-pigs-en.pdf

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