Flordofen 300 mg/ml solution for injection for cattle and pigs

Authorised

- Florfenicol

Product identification

Medicine name:
Flordofen 300 mg/ml solution for injection for cattle and pigs

Active substance:
Florfenicol

Target species:
Pig (for fattening)
Cattle

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:

- **Pig (for fattening)**
  - Meat and offal. 18 day

- **Cattle**
  - Meat and offal. 30 day

Milk: Not authorised for use in animals producing milk for human consumption, including during the dry period.

Subcutaneous use:

- **Cattle**
  - Meat and offal. 44 day

Milk: Not authorised for use in animals producing milk for human consumption, including during the dry period.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01BA90

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

Authorisation status:
Valid

Authorised in:
Greece

Package description:
Brown-coloured type II glass vial of 250 ml, closed by a type I bromobutyl stopper and sealed by an aluminium cap with centre hole.

Colourless type II glass vial of 100 ml, closed by a type I bromobutyl stopper and sealed by an aluminium cap with centre hole.
Colourless type II glass vial of 50 ml, closed by a type I bromobutyl stopper and sealed by an aluminium cap with centre hole.
Polypropylene vial of 250 ml, closed with bromobutyl stopper secured with flip off aluminium collar.

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:
Dopharma Research B.V.

Marketing authorisation date:
24/06/2014

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:
National Organization For Medicines

Authorisation number:
125294/11-12-2018/K-0201501

Date of authorisation status change:
10/12/2018

Reference member state:
Portugal

Procedure number:
PT/V/0112/001

Concerned member states:
Austria Belgium Bulgaria Croatia Czechia Denmark Estonia France Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Poland Romania Slovakia Spain United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents