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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:
Italy

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:
1/04/2014

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:
Ministry Of Health

Authorisation number:
104588

Date of authorisation status change:
13/09/2018

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)

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Documents

Combined File of all Documents

English (PDF)
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