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Spirovet 600 000 iu/ml solution for injection for cattle

Authorised

- Spiramycin

Product identification

Medicine name:
Spirovet 600 000 iu/ml solution for injection for cattle

Active substance:
Spiramycin

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Spiramycin
600000.00 international unit(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**

- Meat and offal. 75 day

Mastitis (30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval).

- Milk. no withdrawal period

Respiratory infections (100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48h of interval). In case of treatment at the dose required for respiratory diseases, the veterinary medicinal product is not authorised for use in animals producing milk for human consumption.

- Meat and offal. 75 day

Respiratory infections (100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48h of interval).

- Milk. 14 day

Mastitis (30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval).

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01FA02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Ireland

Package description:

Box containing 1 glass vial of 50 ml

Box containing 1 plastic vial of 250 ml

Box containing 1 plastic vial of 100 ml
Box containing 1 plastic vial of 50 ml
Box containing 1 glass vial of 250 ml
Box containing 1 glass 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:
Ceva Sante Animale

Marketing authorisation date:
9/11/2012

Manufacturing sites for batch release:
Ceva Sante Animale

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10815/021/001

Date of authorisation status change:
9/11/2012

Reference member state:
France

Procedure number:
FR/V/0244/001

Concerned member states:
Bulgaria Czechia Denmark Estonia Hungary Ireland Latvia Lithuania Poland

Portugal Slovakia Slovenia 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

eu-puar-frv0244001-mr-rpe_77-en.pdf