ROXACIN 100 mg/ml solution for injection for cattle and pigs

Authorised

- Enrofloxacin

Product identification

Medicine name:
ROXACIN 100 mg/ml solution for injection for cattle and pigs
ROXACIN 100 mg/ml SOLUCION INYECTABLE PARA BOVINO Y PORCINO

Active substance:
Enrofloxacin

Target species:
Pig
Cattle

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Enrofloxacin
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Pig**

  - Meat and offal. 13 day

Intravenous use:

- **Cattle**

  - Meat and offal. 5 day

  - Milk. 3 day

Subcutaneous use:

- **Cattle**

  - Meat and offal. 12 day

  - Milk. 4 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01MA90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Spain

Package description:

Type II Amber glass vial of 250 ml capacity closed with pink bromobutyl rubber stopper and aluminium flip-off seal. One vial of 250 ml is available in a cardboard box.

Type II Amber glass vial of 100 ml capacity closed with grey bromobutyl rubber stopper and aluminium flip-off seal. One vial of 100 ml is available in a cardboard box.

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 Calier S.A.

Marketing authorisation date:
25/04/2011

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

Responsible authority:
The Spanish Agency Of Medicines And Medical Devices

Authorisation number:
2287 ESP

Date of authorisation status change:
26/01/2015

Reference member state:
Ireland

Procedure number:
IE/V/0256/001

Concerned member states:
Belgium Germany Greece Hungary Italy Netherlands Poland Portugal Romania Spain

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 3/05/2024
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Package Leaflet

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Labelling

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