

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

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:

Greece

Package description:

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.

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.

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:

6/03/2016

Manufacturing sites for batch release:

Laboratorios Calier S.A.

Responsible authority:

National Organization For Medicines

Authorisation number:

2029/11-01-2017/K-0217601

Date of authorisation status change:

10/01/2017

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

Combined File of all Documents