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

Authorised

- Enrofloxacin

Product identification

Medicine name:
ENRODEXIL 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. 72 hour

Subcutaneous use:

- **Cattle**
  - Meat and offal. 12 day
  - Milk. 96 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01MA90

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

Authorisation status:
Valid

Authorised in:
Romania

Available in:
Romania

Package description:

Type II Amber glass vial of 100 ml capacity closed with grey bromobutyl rubber stopper and aluminium flip-offseal. 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-offseal. 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:
Industrial Veterinaria S.A.

Marketing authorisation date:
2/06/2013

Manufacturing sites for batch release:
Industrial Veterinaria S.A.

Responsible authority:
Institute For Control Of Biological Products And Veterinary Medicines

Authorisation number:
160314

Date of authorisation status change:
13/08/2020

Reference member state:
Ireland

Procedure number:
IE/V/0264/001

Concerned member states:
Austria Belgium Estonia Germany Greece Hungary Italy Netherlands Poland

Portugal Romania 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

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Summary of Product Characteristics