VALEMAS 50 mg/ml solution for injection for cattle, sheep, goats, pigs, dogs and cats.

Authorised

- Enrofloxacin

Product identification

Medicine name:
VALEMAS 50 mg/ml solution for injection for cattle, sheep, goats, pigs, dogs and cats.

Active substance:
Enrofloxacin

Target species:
Pig
Cattle
Dog
Goat
Sheep
Cat

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Enrofloxacin
50.00 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

Subcutaneous use:

- **Cattle**
  - Meat and offal. 12 day
- **Goat**
  - Meat and offal. 6 day
  - Milk. 96 hour
- **Sheep**
  - Meat and offal. 4 day
  - Milk. 72 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01MA90

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

Authorisation status:
Valid

Authorised in:
Ireland

Available in:
Ireland

Package description:
The product is presented in amber Type II glass bottle of 50 ml with chlorobutyl rubber stopper sealed with a flip-off aluminium cap with a tamper-evident polypropylene seal.
The product is presented in amber Type II glass bottle of 100 ml with chlorobutyl rubber stoppers sealed with a flip-off aluminium cap with a tamper-evident polypropylene seal.
The product is presented in amber Type II glass bottle of 250 ml with chlorobutyl rubber stoppers sealed with a flip-off aluminium cap with a tamper-evident polypropylene seal.

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:
Fatro S.p.A.

Marketing authorisation date:
7/06/2019

Manufacturing sites for batch release:
Fatro S.p.A.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10836/005/001

Date of authorisation status change:
7/06/2019

Reference member state:
Ireland

Procedure number:
IE/V/0445/001

Concerned member states:
United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics