Valemas 50 mg/ml Solution for Injection for Cattle, Sheep, Goats, Pigs, Dogs and Cats

• Enrofloxacin

Product identification

Medicine name:

VALEMAS 50 mg/ml solution for injection for cattle, sheep, goats, pigs, dogs and cats. Valemas 50 mg/ml Solution for Injection for Cattle, Sheep, Goats, Pigs, Dogs and Cats

Authorised

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

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- Meat and offal. 13 day

Intravenous use:

Cattle

- Meat and offal. 5 day

Subcutaneous use:

Cattle

- Meat and offal. 12 day

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Dog

Goat

- Meat and offal. 6 day
- Milk. 96 hour

Sheep

- Meat and offal. 4 day

- Milk. 72 hour

Cat

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01MA90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

United Kingdom (Northern Ireland)

Available in:

United Kingdom (Northern 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:

21/05/2019

Manufacturing sites for batch release:

Fatro S.p.A.

Responsible authority:

The Veterinary Medicines Directorate

Authorisation number:

Vm 11557/4003

Date of authorisation status change:

30/08/2022

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

Source URL: https://medicines.health.europa.eu/veterinary/60000046488