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

Authorised

- Marbofloxacin

Product identification

Medicine name:
KELACYL 100 mg/ml solution for injection for cattle and pigs

Active substance:
Marbofloxacin

Target species:
Cattle
Pig (sow)

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

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

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

- **Pig (sow)**
  - Meat and offal. 4 day

- **Cattle**
  - Milk. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

Intravenous use:

- **Cattle**
  - Meat and offal. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

- **Cattle**

- Milk. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

Subcutaneous use:

- **Cattle**
  - Meat and offal. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

- **Cattle**
  - Milk. no withdrawal period

Meat and offal: Respiratory: 3 Days (8 mg/kg (IV/SC/IM)) 6 Days (2 mg/kg (IM)) / Mastitis 3 Days (2 mg/kg (IV/IM/SC)); Milk: Respiratory: 72 Hours (8 mg/g (IM) and 36 Hours (2 mg/g (IV / SC / IM)) / Mastitis: 36 Hours 2 mg/g (IV / IM / SC)

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01MA93

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

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Authorisation status:
Valid

Authorised in:
Belgium

Available in:
Belgium

Package description:
box containing 12 vials of 250 ml individually packed in a carton box

box containing 12 vials of 100 ml individually packed in a carton box
box containing 10 vials of 250 ml individually packed in a carton box
box containing 10 vials of 100 ml individually packed in a carton box
box containing 6 vials of 250 ml individually packed in a carton box
box containing 6 vials of 100 ml individually packed in a carton box
cardboard box containing 1 vial of 250 ml
cardboard box containing 1 vial of 100 ml

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:
KELA Kempisch Laboratorium Kela Laboratoria

Marketing authorisation date:
5/09/2013

Manufacturing sites for batch release:
KELA Kempisch Laboratorium Kela Laboratoria

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V442355

Date of authorisation status change:
5/09/2013

Reference member state:
Spain

Procedure number:
ES/V/0189/001

Concerned member states:
Belgium Germany Luxembourg Poland United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 22/12/2023
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Package Leaflet

English (PDF)
Published on: 22/12/2023
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Labelling

English (PDF)
Published on: 22/12/2023
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Combined File of all Documents

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