Tuloxxin 100 mg/ml solution for injection for cattle, pigs and sheep

Authorised

- Tulathromycin

Product identification

Medicine name:
Tuloxxin 100 mg/ml solution for injection for cattle, pigs and sheep

Active substance:
Tulathromycin

Target species:
Sheep
Pig
Cattle

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:
Tulathromycin

100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Sheep**
  - Meat and offal. 16 day
- **Pig**
  - Meat and offal. 13 day

Subcutaneous use:

- **Cattle**
  - Meat and offal. 22 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA94

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

Authorisation status:
Valid

Authorised in:
Slovenia

Available in:
Slovenia

Package description:
Type I clear glass bottle of 250 ml with Type I chlorobutyl/butyl film laminated rubber stopper and aluminium cap with plastic tear/flip-off tab, in a cardboard box.

Type I clear glass bottle of 100 ml with Type I chlorobutyl/butyl film laminated rubber stopper and aluminium caps with plastic tear/flip-off tab, in a cardboard box.
Type I clear glass bottle of 50 ml with Type I chlorobutyl/butyl film laminated rubber stopper and aluminium cap with plastic tear/flip-off tab, 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:
KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:
3/01/2019

Manufacturing sites for batch release:
TAD Pharma GmbH
KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
DC/V/0647/001

Date of authorisation status change:
3/01/2019

Reference member state:
Ireland

Procedure number:
IE/V/0396/001

Concerned member states:

Belgium Bulgaria Croatia Czechia Estonia France Germany Greece Hungary Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia Spain 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: 3/05/2024
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Package Leaflet

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Labelling

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