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

Authorised

- Tulathromycin

Product identification

Medicine name:
Tulieve 100 mg/ml solution for injection for cattle, pigs and sheep
Tulieve 100 mg/ml Injektionslösung für Rinder, Schweine und Schafe

Active substance:
Tulathromycin

Target species:
Cattle
Sheep
Pig

Route of administration:
Subcutaneous use
Intramuscular 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:
Subcutaneous use:

- **Cattle**
  - Meat and offal. 22 day
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

Intramuscular use:

- **Sheep**
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

  - Meat and offal. 16 day

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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA94

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

Authorisation status:

Valid

Authorised in:
Germany

Package description:
(ID9) 500 millilitre(s): Box (board) with 1 Vial (clear glass) with 500 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID8) 250 millilitre(s): Box (board) with 1 Vial (clear glass) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID7) 100 millilitre(s): Box (board) with 1 Vial (clear glass) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID6) 50 millilitre(s): Box (board) with 1 Vial (clear glass) with 50 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID5) 1 litre(s): Box (board) with 1 Vial (high-density polyethylene) with 1 litre(s), closed with Stopfen (bromobutyl rubber)
(ID4) 500 millilitre(s): Box (board) with 1 Vial (high-density polyethylene) with 500 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID3) 250 millilitre(s): Box (board) with 1 Vial (high-density polyethylene) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID2) 100 millilitre(s): Box (board) with 1 Vial (high-density polyethylene) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber)
(ID1) 50 millilitre(s): Box (board) with 1 Vial (high-density polyethylene) with 50 millilitre(s), closed with Stopfen (bromobutyl rubber)

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:
Norbrook Laboratories (Ireland) Limited

Marketing authorisation date:
25/03/2020

Manufacturing sites for batch release:
Norbrook Laboratories Limited
Norbrook Laboratories (Ireland) Limited

Responsible authority:
Federal Office Of Consumer Protection And Food Safety

Authorisation number:
402669.00.00

Date of authorisation status change:
25/03/2020

Reference member state:
Germany

Procedure number:
DE/V/0322/001

Concerned member states:
Belgium Estonia France Hungary Ireland Italy Latvia Lithuania Netherlands Poland Portugal 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

English (PDF)
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