

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

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:

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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:

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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

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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:

Estonia

Package description:

(ID1) 50 millilitre(s): Box (cardboard) with 1 Vial (high-density polyethylene) with 50 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID2) 100 millilitre(s): Box (cardboard) with 1 Vial (high-density polyethylene) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID3) 250 millilitre(s): Box (cardboard) with 1 Vial (high-density polyethylene) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID4) 500 millilitre(s): Box (cardboard) with 1 Vial (high-density polyethylene) with 500 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID5) 1 litre(s): Box (cardboard) with 1 Vial (high-density polyethylene) with 1 litre(s), closed with Stopfen (bromobutyl rubber)

(ID6) 50 millilitre(s): Box (cardboard) with 1 Vial (clear glass) with 50 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID7) 100 millilitre(s): Box (cardboard) with 1 Vial (clear glass) with 100 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID8) 250 millilitre(s): Box (cardboard) with 1 Vial (clear glass) with 250 millilitre(s), closed with Stopfen (bromobutyl rubber)

(ID9) 500 millilitre(s): Box (cardboard) with 1 Vial (clear glass) with 500 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:

30/03/2020

Manufacturing sites for batch release:

Norbrook Laboratories Limited
Norbrook Laboratories (Ireland) Limited

Responsible authority:

State Agency Of Medicines

Authorisation number:

2232

Date of authorisation status change:

30/03/2020

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

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Combined File of all Documents

2492669-paren-20210108.pdf