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

Authorised

- Tulathromycin

Product identification

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

Active substance:
Tulathromycin

Target species:
Cattle
Pig
Sheep

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

Milk: 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

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Intramuscular use:

- **Pig**
  - Meat and offal. 13 day
- **Sheep**
  - Meat and offal. 16 day
  - Milk. no withdrawal period

Milk: 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
- Milk. no withdrawal period

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- Meat and offal. 16 day
- Milk. no withdrawal period

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- Meat and offal. 16 day
- Milk. no withdrawal period

Milk: 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

- **Sheep**
  - Meat and offal. 16 day
  - Milk. no withdrawal period

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- Meat and offal. 16 day
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- Milk. no withdrawal period

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Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA94

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

Authorisation status:
Valid

Authorised in:
Italy

Package description:
cardboard box containing 1 vial of 50 ml
cardboard box containing 1 vial of 100 ml
cardboard box containing 1 vial of 250 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:

Alivira Animal Health Limited

Marketing authorisation date:
28/12/2020

Manufacturing sites for batch release:
Laboratorios Karizoo S.A.

Responsible authority:
Ministry Of Health

Authorisation number:
105465

Date of authorisation status change:
28/12/2020

Reference member state:
Spain

Procedure number:
ES/V/0373/001

Concerned member states:
Belgium Cyprus Estonia France Germany Greece Hungary Italy Latvia Lithuania Netherlands Poland Portugal Romania

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Documents

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics

Labelling

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