

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:

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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

- 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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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:

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Pig

- Meat and offal. 13 day

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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

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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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

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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:

Belgium

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:

30/11/2020

Manufacturing sites for batch release:

Laboratorios Karizoo S.A.

Responsible authority:

Federal Agency For Medicines And Health Products

Authorisation number:

BE-V575217

Date of authorisation status change:

30/11/2020

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

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)

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Combined File of all Documents

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