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

Not authorised

- Tulathromycin

Product identification

Medicine name:
Doraxx 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

- **Cattle**
  - 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

Intramuscular use:

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

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

- **Sheep**
  - 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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA94

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

Authorisation status:
Surrendered

Authorised in:
Lithuania

Package description:
Cardboard box with 1 vial of 250 ml
Cardboard box with 1 vial of 100 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:
Dopharma Research B.V.

Marketing authorisation date:
14/04/2021

Manufacturing sites for batch release:
Mevet S.A.
Dopharma B.V.

Responsible authority:
State Food And Veterinary Service

Authorisation number:
LT/2/21/2655/001-002

Date of authorisation status change:
11/04/2021

Reference member state:
Spain

Procedure number:
ES/V/0390/001

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Package Leaflet

Labelling

Combined File of all Documents

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RV2655.pdf