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

Authorised

- Tulathromycin

Product identification

Medicine name:
Doraxx 100 mg/ml solution for injection for cattle, pigs and sheep
Doraxx 100 mg/ml oplossing voor injectie voor runderen, varkens en schapen

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:
Valid

Authorised in:
Netherlands

Available in:
Netherlands

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:
29/04/2021

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

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 126606

Date of authorisation status change:
22/02/2022

Reference member state:
Spain

Procedure number:
ES/V/0390/001

Concerned member states:
Austria Belgium Bulgaria Denmark Estonia France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal Romania 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

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

Summary of Product Characteristics

Package Leaflet

Labelling

eu-PUAR-doraxx-100-mg-ml-solution-for-injection-for-cattle--pigs-and-sheep-en.pdf