

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

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

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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:

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Pig

- Meat and offal. 13 day

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Sheep

- Meat and offal. 16 day

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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:

Spain

Package description:

Available only in Spanish

Available only in Spanish

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:

2/06/2021

Manufacturing sites for batch release:

Mevet S.A.

Dopharma B.V.

Responsible authority:

Spanish Agency Of Medicines And Medical Devices

Authorisation number:

4020 ESP

Date of authorisation status change:

3/06/2021

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

Summary of Product Characteristics

English (PDF)

Published on: 12/04/2023

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Package Leaflet

English (PDF)

Published on: 12/04/2023

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Labelling

English (PDF)

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