

# 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 injektionsvæske, opløsning

**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

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**Withdrawal period by route of administration:****Subcutaneous use:****• Cattle**

- Meat and offal. 22 day
- Milk. no withdrawal period

Meat and offal: 22 days; 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**

- Milk. no withdrawal period

Meat and offal: 16 days; 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
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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QJ01FA94

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Denmark

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**Package description:**

Cardboard box with 1 vial of 250 ml

Cardboard box with 1 vial of 100 ml

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Dopharma Research B.V.

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**Marketing authorisation date:**

6/05/2021

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**Manufacturing sites for batch release:**

Mevet S.A.U.

Dopharma B.V.

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**Responsible authority:**

Danish Medicines Agency

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**Authorisation number:**

64263

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**Date of authorisation status change:**

6/05/2021

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**Reference member state:**

Spain

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**Procedure number:**

ES/V/0390/001

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**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)

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To consult adverse reactions on veterinary medicinal products please go to [www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

English (PDF)

Published on: 12/04/2023

[Download](#)

### Package Leaflet

### Labelling

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

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