

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 solução injetável para bovinos, suínos e ovinos

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
- 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

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Portugal

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:

22/04/2021

Manufacturing sites for batch release:

Mevet S.A.U.

Dopharma B.V.

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

1420/01/21DFVPT

Date of authorisation status change:

22/04/2021

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

Package Leaflet

Labelling

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

Source URL: <https://medicines.health.europa.eu/veterinary/600000083040>