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DOPHATYL-JECT 200 000 IU/ML SOLUTION FOR INJECTION FOR CATTLE, SHEEP, GOATS AND PIGS

Authorised

- Tylosin

Product identification

Medicine name:
DOPHATYL-JECT 200 000 IU/ML SOLUTION FOR INJECTION FOR CATTLE, SHEEP, GOATS AND PIGS

Active substance:
Tylosin

Target species:
Cattle
Pig
Sheep
Goat

Route of administration:
Intramuscular use
Intravenous use

Product details

Active substance and strength:
Tylosin
200000.00 international unit(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 28 day
  - Milk. 108 hour
- **Pig**
  - Meat and offal. 16 day
- **Sheep**
  - Meat and offal. 42 day
  - Milk. 108 hour
- **Goat**
  - Meat and offal. 42 day
  - Milk. 108 hour

Intravenous use:

- **Cattle**
  - Meat and offal. 28 day
  - Milk. 108 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA90

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

Authorisation status:
Valid

Authorised in:
Sweden

Available in:
Sweden

Package description:
Cardboard box with 1 colourless, type I glass vial of 100 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.
Cardboard box with 1 colourless, type I glass vial of 50 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:
Dopharma Research B.V.

Marketing authorisation date:
14/05/2024

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:

Swedish Medical Products Agency

Authorisation number:
64720

Date of authorisation status change:
14/05/2024

Reference member state:
France

Procedure number:
FR/V/0477/001

Concerned member states:
Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Norway Poland Portugal Romania Slovakia Spain Sweden

Generic of:
600000035545

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

Documents

Summary of Product Characteristics

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

Package Leaflet

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

Labelling

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

Combined File of all Documents

eu-puar-frv0477001-mr-rpe840-en.pdf