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:
Denmark

Available in:
Denmark

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:
29/04/2024

Manufacturing sites for batch release:
Dopharma B.V.

Responsible authority:

Danish Medicines Agency

Authorisation number:
69515

Date of authorisation status change:
29/04/2024

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

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Combined File of all Documents

English (PDF)
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