Emdogent 100 mg/ml Oplossing voor injectie

Authorised

- Gentamicin sulfate

Product identification

Medicine name:
Emdogent 100 mg/ml Oplossing voor injectie

Active substance:
Gentamicin sulfate

Target species:
Cattle
Dog
Horse

Route of administration:
Intramuscular use
Subcutaneous use
Intravenous use

Product details

Active substance and strength:
Gentamicin sulfate
1.00 million international units / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 214 day

Due to accumulation of gentamicin in liver, kidneys and injection site, any repeated course of treatment during the withdrawal period must be avoided

  - Milk. 7 day

Intravenous use:

- **Cattle**
  - Meat and offal. 214 day

Due to accumulation of gentamicin in liver, kidneys and injection site, any repeated course of treatment during the withdrawal period must be avoided

  - Milk. 7 day

- **Horse**
  - Meat and offal. no withdrawal period

Do not use in animals aimed at human consumption

  - Milk. no withdrawal period

Do not use in animals producing milk for human consumption

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01GB03

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

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Authorisation status:

Valid

Authorised in:
Belgium

Available in:
Belgium

Package description:
Emdogent 12 Vials with 100 ml of Solution for injection
Emdogent 1 Vial with 100 ml of Solution for injection

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Emdoka

Marketing authorisation date:
9/03/2018

Manufacturing sites for batch release:
Produlab Pharma B.V.

Responsible authority:
Federal Agency For Medicines And Health Products

Authorisation number:
BE-V526640

Date of authorisation status change:
1/06/2021

Generic of:
600000072932

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

Documents

Summary of Product Characteristics

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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.