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GentaDug 85 mg/ml solution for injection for horses, cattle, pigs, dogs and cats

Authorised

- Gentamicin sulfate

Product identification

Medicine name:
GentaDug 85 mg/ml solution for injection for horses, cattle, pigs, dogs and cats

Active substance:
Gentamicin sulfate

Target species:
Cattle
Dog
Cat
Pig
Horse

Route of administration:
Intramuscular use
Intravenous use
Subcutaneous use

Product details

Active substance and strength:
Gentamicin sulfate
85.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Cattle**
  - Meat and offal. 214 day
  - Meat and offal. 192 day Calves
  - Milk. 7 day
- **Pig**
  - Meat and offal. 146 day

Intravenous use:

- **Cattle**
  - Meat and offal. 214 day
  - Meat and offal. 192 day Calves
  - Milk. 7 day
- **Pig**
  - Meat and offal. 146 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01GB03

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

Authorisation status:
Valid

Authorised in:
Ireland

Available in:
Ireland

Package description:
100 ml clear glass vials with bromobutyl rubber stoppers and aluminium caps, packaged in a cardboard box. Presentation 1 x 100 ml
100 ml clear glass vials with bromobutyl rubber stoppers and aluminium caps, packaged in a cardboard box. Presentation 6 x 100 ml
100 ml clear glass vials with bromobutyl rubber stoppers and aluminium caps, packaged in a cardboard box. Presentation 12 x 100 ml

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Bela-Pharm GmbH & Co. KG

Marketing authorisation date:
4/08/2023

Manufacturing sites for batch release:
Bela-Pharm GmbH & Co. KG

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA10445/008/001

Date of authorisation status change:
4/08/2023

Reference member state:
Ireland

Procedure number:
IE/V/0772/001

Concerned member states:
United Kingdom (Northern Ireland)

Generic of:
600000072858

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

Documents

Summary of Product Characteristics

ie-puar-mr-iev0772001-gentadug-85-mgml-solution-for-injection-for-horses-en.pdf