Gamrozyne 150 mg/ml Solution for Injection for Cattle, Sheep and Pigs

Authorised

- Gamithromycin

Product identification

Medicine name:
Gamrozyne 150 mg/ml Solution for Injection for Cattle, Sheep and Pigs
GAMROZYNE 150 mg/ml SOLUCION INYECTABLE PARA BOVINO, OVINO Y PORCINO

Active substance:
Gamithromycin

Target species:
Pig
Cattle
Sheep

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:

Gamithromycin
150.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig**
  - Meat and offal. 16 day

Subcutaneous use:

- **Cattle**
  - Meat and offal. 64 day
- **Sheep**
  - Meat and offal. 29 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA95

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

Authorisation status:
Valid

Authorised in:
Spain

Package description:
Type 1 glass vials of 100 ml with a chlorobutyl rubber stopper and an aluminium seal.Cardboard box containing 1 vial of 100 ml.
Type 1 glass vials of 250 ml with a chlorobutyl rubber stopper and an aluminium seal.Cardboard box containing 1 vial of 250 ml.

Type 1 glass vials of 500 ml with a chlorobutyl rubber stopper and an aluminium seal.Cardboard box containing 1 vial of 500 ml.

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Bimeda Animal Health Limited

Marketing authorisation date:
3/10/2024

Manufacturing sites for batch release:
Bimeda Animal Health Limited

Responsible authority:
Spanish Agency Of Medicines And Medical Devices

Authorisation number:
4352 ESP

Date of authorisation status change:
4/10/2024

Reference member state:
Ireland

Procedure number:
IE/V/0883/001

Concerned member states:
Denmark France Spain Sweden United Kingdom (Northern Ireland)

Generic of:

600000004401

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.