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LABIMYCIN LA 300 mg/ml SOLUTION FOR INJECTION

Authorised

- Oxytetracycline dihydrate

Product identification

Medicine name:
LABIMYCIN LA 300 mg/ml SOLUTION FOR INJECTION

Active substance:
Oxytetracycline dihydrate

Target species:
Pig
Cattle
Sheep

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Oxytetracycline dihydrate
323.50 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Pig**
  - Meat and offal. 28 day
- **Cattle**
  - Meat and offal. 35 day
  - Milk. 10 day
- **Sheep**
  - Meat and offal. 35 day
  - Milk. 9 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01AA06

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Luxembourg

Available in:

Luxembourg

Package description:

Box with 10 Vials of 250 ml

Box with 10 Vials of 100 ml

Box with 12 Vials of 50 ml

Box with 1 vial of 250 ml

Box with 1 vial of 100 ml
Box with 1 Vial of 50 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Labiana Life Sciences S.A.

Marketing authorisation date:
21/02/2025

Manufacturing sites for batch release:
Labiana Life Sciences S.A.

Responsible authority:
Labiana Life Sciences S.A.

Authorisation number:
V/006/21/02/2025

Date of authorisation status change:
21/02/2025

Reference member state:
Spain

Procedure number:
ES/V/0406/001

Concerned member states:
Belgium Denmark France Germany Greece Hungary Ireland Italy Luxembourg Netherlands Portugal Romania

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

Documents

Combined File of all Documents

Summary of Product Characteristics

Package Leaflet

Labelling

eu-PUAR-esv0406001-dcp-labimycin-la-300-mg-ml-solution-for-injection-en.pdf