LABIMYCIN LA 300 mg/ml SOLUTION FOR INJECTION

Authorised

• Oxytetracycline dihydrate

Product identification

Medicine name:

LABIMYCIN LA 300 mg/ml SOLUTION FOR INJECTION Labimycin LA 300 mg/ml soluzione iniettabile

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. 7 day

Sheep

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- Meat and offal. 35 day
- Milk. 9 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01AA06

Legal status of supply:

Medicinal product subject to special medical prescription

Authorisation status:

Valid

Authorised in:

Italy

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:

30/01/2025

Manufacturing sites for batch release:

Labiana Life Sciences S.A.

Responsible authority: European Medicines Agency

Authorisation number: 105842

Date of authorisation status change: 28/10/2024

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

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