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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:

Withdrawal period by route of administration: Intramuscular use:

•

Pig

- Meat and offal. 28 day

•

Cattle

- Meat and offal. 35 day
- Milk. 7 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

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