

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:

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Pig

- Meat and offal. 28 day

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Cattle

- Meat and offal. 35 day

- Milk. 10 day

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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:

Ireland

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:

23/08/2024

Manufacturing sites for batch release:

Labiana Life Sciences S.A.

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10402/008/001

Date of authorisation status change:

23/08/2024

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

Summary of Product Characteristics

Package Leaflet

Labelling

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