LABIXXIN 100MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND SHEEP

Authorised

- Tulathromycin

Product identification

Medicine name:
LABIXXIN 100MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND SHEEP
Labixxin, 100 mg/mL, otopina za injekciju, za goveda, svinje i ovce

Active substance:
Tulathromycin

Target species:
Pig
Sheep
Cattle

Route of administration:
Intramuscular use
Subcutaneous use

Product details

Active substance and strength:

Tulathromycin
100.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Solution for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Pig**
  - Meat and offal. 13 day

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

- **Sheep**
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

Subcutaneous use:

- **Cattle**
  - Meat and offal. 22 day

- **Cattle**
  - Milk. no withdrawal period

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ01FA94

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

Authorisation status:
Valid

Authorised in:
Croatia

Package description:
Cardboard box containing 1 vial of 250 ml
Cardboard box containing 1 vial of 100 ml
Cardboard box containing 1 vial of 50 ml
Cardboard box containing 1 vial of 20 ml
Cardboard box containing 10 vials of 250 ml
Cardboard box containing 10 vials of 100 ml
Cardboard box containing 12 vials of 50 ml
Cardboard box containing 12 vials of 20 ml

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Labiana Life Sciences S.A.

Marketing authorisation date:
24/11/2023

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

Responsible authority:
Ministry Of Agriculture Veterinary And Food Safety Directorate

Authorisation number:
UP/I-322-05/23-01/775

Date of authorisation status change:
24/11/2023

Reference member state:
Spain

Procedure number:
ES/V/0423/001

Concerned member states:
Croatia

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 27/06/2024
Download

Package Leaflet

Labelling

eu-PUAR-esv0423001-dcp-labixxin-100mg-ml-solution-for-injection-for-cattle--pigs-and-sheep-en.pdf