Troxxan100 mg/ml solution for injection for catlle, pigs and sheeps

Authorised

- Tulathromycin

Product identification

Medicine name:
Troxxan100 mg/ml solution for injection for catlle, pigs and sheeps
TROXXAN 100 MG/ML SOLUTION INJECTABLE POUR BOVINS, PORCINS ET OVINS

Active substance:
Tulathromycin

Target species:
Cattle
Pig
Sheep

Route of administration:
Subcutaneous use
Intramuscular 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:
Subcutaneous use:

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

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

Milk: 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

Intramuscular use:

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

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

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

Milk: 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:
France

Package description:
cardboard box containing 1 vial of 250 ml
cardboard box containing 1 vial of 100 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:
Laboratorios Syva S.A.

Marketing authorisation date:
18/03/2021

Manufacturing sites for batch release:
Laboratorios Syva S.A.

Responsible authority:
French Agency For Food, Environmental And Occupational Health & Safety

Authorisation number:
FR/V/4516674 1/2021

Date of authorisation status change:
18/03/2021

Reference member state:

Spain

Procedure number:
ES/V/0392/001

Concerned member states:
Austria Belgium Bulgaria Czechia Denmark France Germany Greece Hungary Ireland Italy Netherlands Poland Portugal Romania Slovakia United Kingdom (Northern Ireland)

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

Documents

Summary of Product Characteristics

English (PDF)
Published on: 22/12/2023
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Package Leaflet

Labelling

Combined File of all Documents

eu-PUAR-esv0392001-dcp-troxxan100-mg-ml-solution-for-injection-for-catlle--pigs-and-sheeps-en.pdf