Santiola 50 mg/ml solution for injection for cattle and sheep

Not authorised

- Closantel sodium dihydrate

Product identification

Medicine name:
Santiola 50 mg/ml solution for injection for cattle and sheep
Santiola 50 mg/ml raztopina za injiciranje za govedo in ovce

Active substance:
Closantel sodium dihydrate

Target species:
Cattle
Sheep

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Closantel sodium dihydrate
54.38 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration:

Subcutaneous use:

- **Cattle**
  - Meat and offal. 77 day
- **Sheep**
  - Meat and offal. 107 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP52AG09

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

Authorisation status:
Surrendered

Authorised in:
Slovenia

Package description:
Container or pack size: 4 type I amber glass vials. Closure: bromobutyl rubber.
Contents of each vial: 250 ml solution.
Container or pack size: 1 type I amber glass vial. Closure: bromobutyl rubber.
Contents of each vial: 250 ml solution.

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:
KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:
20/12/2017

Manufacturing sites for batch release:
KRKA tovarna zdravil d.d. Novo mesto
TAD Pharma GmbH

Responsible authority:
Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

Authorisation number:
DC/V/0595/001

Date of authorisation status change:
7/01/2022

Reference member state:
Ireland

Procedure number:
IE/V/0377/001

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