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# 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:**

# Withdrawal period by route of administration:

**Subcutaneous use:** 

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#### **Cattle**

- Meat and offal. 77 day

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#### 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