

# SPIROVET 600 000 IU/ML SOLUTION FOR INJECTION FOR CATTLE

Authorised

- Spiramycin

## Product identification

**Medicine name:**

SPIROVET 600 000 IU/ML SOLUTION FOR INJECTION FOR CATTLE  
Spirovet 600 000 IE/ml raztopina za injiciranje za govedo

**Active substance:**

Spiramycin

**Target species:**

Cattle

**Route of administration:**

Intramuscular use

## Product details

**Active substance and strength:**

Spiramycin  
600000.00 international unit(s) / 1.00 millilitre(s)

**Pharmaceutical form:**

Solution for injection

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**Withdrawal period by route of administration:****Intramuscular use:**

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**Cattle**

- Meat and offal. 75 day

Mastitis (30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval).

- Milk. no withdrawal period

Respiratory infections (100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48h of interval). In case of treatment at the dose required for respiratory diseases, the veterinary medicinal product is not authorised for use in animals producing milk for human consumption.

- Meat and offal. 75 day

Respiratory infections (100 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 30 kg bodyweight) twice at 48h of interval).

- Milk. 14 day

Mastitis (30 000 IU of spiramycin per kg bodyweight (i.e. 5 ml of product per 100 kg bodyweight) twice at 24h of interval).

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**Anatomical therapeutic chemical veterinary (ATCvet) codes:**

QJ01FA02

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**Legal status of supply:**

Veterinary medicinal product subject to veterinary prescription

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**Authorisation status:**

Valid

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**Authorised in:**

Slovenia

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**Package description:**

Box containing 1 glass vial of 50 ml  
Box containing 1 plastic vial of 250 ml  
Box containing 1 plastic vial of 100 ml  
Box containing 1 plastic vial of 50 ml  
Box containing 1 glass vial of 250 ml  
Box containing 1 glass vial of 100 ml

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## Additional information

**Entitlement type:**

Marketing Authorisation

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**Legal basis of product authorisation:**

Generic application (Article 13(1) of Directive No 2001/82/EC)

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**Marketing authorisation holder:**

Ceva Sante Animale

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**Marketing authorisation date:**

17/07/2012

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**Manufacturing sites for batch release:**

CEVA SANTE ANIMALE - LIBOURNE

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**Responsible authority:**

Agency For Medicinal Products And Medical Devices Of The Republic Of Slovenia

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**Authorisation number:**

MR/V/0399/001

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**Date of authorisation status change:**

17/07/2012

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**Reference member state:**

France

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**Procedure number:**

FR/V/0244/001

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**Concerned member states:**

Bulgaria Czechia Denmark Estonia Hungary Ireland Latvia Lithuania Poland  
Portugal Slovakia Slovenia United Kingdom (Northern Ireland)

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To consult adverse reactions on veterinary medicinal products please go to  
[www.adrreports.eu/vet](http://www.adrreports.eu/vet)

## Documents

### Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

### Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

### Labelling

This document does not exist in this language (English). You can find it in another language below.