SELECTAN 300 mg/ml solution for injection for cattle and swine

• Florfenicol

Product identification

Medicine name:

SELECTAN 300 mg/ml solution for injection for cattle and swine FLORSELECT VET. 300 mg/ml Stungulyf, lausn Nautgripir og svín

Active substance:

Florfenicol

Target species:

Cattle

Pig

Route of administration:

Intramuscular use

Product details

Active substance and strength:

Florfenicol 300.00 milligram(s) / 1.00 millilitre(s)

Pharmaceutical form:

Solution for injection

Withdrawal period by route of administration: Intramuscular use:

Cattle - Meat and offal. 30 day

Pig

- Meat and offal. 18 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01BA90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Iceland

Package description:

The product is bottled in 50 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.One bottle of 50 ml is available in a cardboard box.

The product is bottled in 100 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.One bottle of 100 ml is available in a cardboard box.

The product is bottled in 250 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.One bottle of 250 ml is available in a cardboard box.

The product is bottled in 100 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size:10 x 100 ml

The product is bottled in 250 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size:10 x 250 ml.

The product is bottled in 100 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size: 12×100 ml.

The product is bottled in 250 ml plastic bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size: 12 x 250 ml.

The product is bottled in 100 ml colourless Type II glass bottle, closed with Type I polymeric elastomer stopper with aluminium cap.One bottle of 100 ml is available in a cardboard box.

The product is bottled in 100 ml colourless Type II glass bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size:10 x 100 ml The product is bottled in 100 ml colourless Type II glass bottle, closed with Type I polymeric elastomer stopper with aluminium cap.Clinical pack size:12 x 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 Hipra S.A.

Marketing authorisation date:

20/05/2011

Manufacturing sites for batch release:

Laboratorios Hipra, S.A.

Responsible authority: Icelandic Medicines Agency

Authorisation number: IS/2/11/015/01

Date of authorisation status change: 26/11/2012

Reference member state: Ireland

Procedure number: IE/V/0189/001

Concerned member states:

Austria Belgium Bulgaria Cyprus Czechia Denmark Estonia Finland France Germany Greece Hungary Iceland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

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