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Biocan Novel Pi L4, Lyophilisate and solvent for suspension for injection

Authorised

- Canine parainfluenza virus, strain CPiV-2-Bio 15, Live
- Leptospira interrogans, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated
- Leptospira interrogans, serovar Canicola, strain MSLB 1090, Inactivated
- Leptospira interrogans, serovar Bratislava, strain MSLB 1088, Inactivated
- Leptospira kirschneri, serovar Grippotyphosa, strain MSLB 1091, Inactivated

Product identification

Medicine name:
Biocan Novel Pi L4, Lyophilisate and solvent for suspension for injection

Active substance:
Canine parainfluenza virus, strain CPiV-2-Bio 15, Live
Leptospira interrogans, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated
Leptospira interrogans, serovar Canicola, strain MSLB 1090, Inactivated
Leptospira interrogans, serovar Bratislava, strain MSLB 1088, Inactivated
Leptospira kirschneri, serovar Grippotyphosa, strain MSLB 1091, Inactivated

Target species:

Dog

Route of administration:
Subcutaneous use

Product details

Active substance and strength:
Canine parainfluenza virus, strain CPiV-2-Bio 15, Live
5.10 log10 50% tissue culture infectious dose / 1.00 Dose

Leptospira interrogans, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated
51.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Leptospira interrogans, serovar Canicola, strain MSLB 1090, Inactivated
51.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Leptospira interrogans, serovar Bratislava, strain MSLB 1088, Inactivated
51.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Leptospira kirschneri, serovar Grippotyphosa, strain MSLB 1091, Inactivated
40.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Pharmaceutical form:
Lyophilisate and solvent for suspension for injection

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI07AI08

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

Authorisation status:
Valid

Authorised in:
Slovakia

Package description:
Glass Vial 10 x 1.0 Dose
Glass Vial 25 x 1.0 Dose
Glass Vial 50 x 1.0 Dose

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Bioveta a.s.

Marketing authorisation date:
9/02/2015

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Institute For State Control Of Veterinary Biologicals And Medicaments

Authorisation number:
97/004/DC/15-S

Date of authorisation status change:
9/02/2015

Reference member state:
Czechia

Procedure number:
CZ/V/0123/001

Concerned member states:
Bulgaria Croatia Cyprus Estonia Hungary Latvia Lithuania Poland Romania Slovakia Slovenia

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

Documents

Combined File of all Documents

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