

Biocan Novel DHPPI/L4R, Lyophilisate and solvent for suspension for injection

Authorised

- Canine distemper virus, strain CDV Bio 11/A, Live
- Canine adenovirus 2, strain CAV-2-Bio 13, Live
- Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live
- Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live
- Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar Icterohaemorrhagiae, strain MSLB 1089, Inactivated
- Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090, Inactivated
- Rabies virus, strain SAD Vnukovo-32, Inactivated
- Leptospira interrogans, serogroup Australis, serovar Bratislava, Inactivated
- Leptospira kirschneri, Serogroup Grippotyphosa, Inactivated

Product identification

Medicine name:

Biocan Novel DHPPI/L4R, Lyophilisate and solvent for suspension for injection
Biocan Novel DHPPI/L4R, süstesuspensiooni lüofilisaat ja suspensioon koertele

Active substance:

Canine distemper virus, strain CDV Bio 11/A, Live
Canine adenovirus 2, strain CAV-2-Bio 13, Live
Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live

Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live

Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar
Icterohaemorrhagiae, strain MSLB 1089, Inactivated

Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090,
Inactivated

Rabies virus, strain SAD Vnukovo-32, Inactivated

Leptospira interrogans, serogroup Australis, serovar Bratislava, Inactivated

Leptospira kirschneri, Serogroup Grippotyphosa, Inactivated

Target species:

Dog

Route of administration:

Subcutaneous use

Product details

Active substance and strength:

Canine distemper virus, strain CDV Bio 11/A, Live

5.10 log₁₀ tissue culture infective dose 50 / 1.00 Dose

Canine adenovirus 2, strain CAV-2-Bio 13, Live

5.30 log₁₀ tissue culture infective dose 50 / 1.00 Dose

Canine parvovirus 2b, strain CPV-2b Bio 12/B, Live

6.60 log₁₀ tissue culture infective dose 50 / 1.00 Dose

Canine parainfluenza virus 2, strain CPiV-2-Bio 15, Live

5.10 log₁₀ tissue culture infective dose 50 / 1.00 Dose

Leptospira interrogans, serogroup Icterohaemorrhagiae, serovar
Icterohaemorrhagiae, strain MSLB 1089, Inactivated

51.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Leptospira interrogans, serogroup Canicola, serovar Canicola, strain MSLB 1090,
Inactivated

51.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Rabies virus, strain SAD Vnukovo-32, Inactivated

2.00 international unit(s) / 1.00 Dose

Leptospira interrogans, serogroup Australis, serovar Bratislava, Inactivated
51.00 Antibody microagglutination-lytic reaction / 1.00 Dose
Leptospira kirschneri, Serogroup Grippotyphosa, Inactivated
40.00 Antibody microagglutination-lytic reaction / 1.00 Dose

Pharmaceutical form:

Lyophilisate and solvent for suspension for injection

Withdrawal period by route of administration:

Subcutaneous use:

- Dog
-

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI07AJ06

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Estonia

Package description:

Glass Vial 50 x 1.0 Dose

Glass Vial 25 x 1.0 Dose

Glass Vial 10 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:

19/09/2014

Manufacturing sites for batch release:

Bioveta a.s.

Responsible authority:

State Agency Of Medicines

Authorisation number:

1858

Date of authorisation status change:

19/09/2014

Reference member state:

Czechia

Procedure number:

CZ/V/0119/001

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

Summary of Product Characteristics

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