

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**PLASTIC BOX****(25x1, 10x1 or 50x1 dose presentations)****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Biocan Novel DHPPi/L4R, lyophilisate and suspension for suspension for injection for dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose (1 ml) contains:

Active substances:Lyophilisate (live attenuated)

	Minimum	Maximum
Canine Distemper virus, strain CDV Bio 11/A	$10^{3.1}$ TCID ₅₀	$10^{5.1}$ TCID ₅₀
Canine Adenovirus type 2, strain CAV-2 Bio 13	$10^{3.6}$ TCID ₅₀	$10^{5.3}$ TCID ₅₀
Canine Parvovirus type 2b, strain CPV-2b Bio 12/B	$10^{4.3}$ TCID ₅₀	$10^{6.6}$ TCID ₅₀
Canine Parainfluenza type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ TCID ₅₀	$10^{5.1}$ TCID ₅₀

Suspension (inactivated)

<i>Leptospira interrogans</i> serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain MSLB 1089	GMT \geq 1:51 ALR
<i>Leptospira interrogans</i> serogroup Canicola serovar Canicola, strain MSLB 1090	GMT \geq 1:51 ALR
<i>Leptospira kirschneri</i> serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	GMT \geq 1:40 ALR
<i>Leptospira interrogans</i> serogroup Australis serovar Bratislava, strain MSLB 1088	GMT \geq 1:51 ALR
Inactivated rabies virus, strain SAD Vnukovo-32	> 2.0 IU

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

10/25/50 x 1 dose (1 ml vial of each fraction).

5. TARGET SPECIES

Dogs.

6. INDICATION(S)**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

(1 dose lyophilisate vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel DHPPi/L4R lyophilisate for dogs



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

CDV, CAV-2, CPV-2b and CPiV-2

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

sc

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

(1 ml suspension vials)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel DHPPi/L4R suspension for dogs



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L.i. serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, *L.i.* serogroup Canicola serovar Canicola, *L.k.* serogroup Grippotyphosa serovar Grippotyphosa, *L.i.* serogroup Australis serovar Bratislava and rabies.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

sc

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.