

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

PLASTIC BOX

(10x1, 25x1 or 50x1 dose presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel DHPPi/L4, lyophilisate and suspension for suspension for injection for dogs.



2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:

Active substances:

Lyophilisate (live attenuated)

Canine Distemper virus, strain CDV Bio 11/A

Canine Adenovirus type 2, strain CAV-2 Bio 13

Canine Parvovirus type 2b, strain CPV-2b Bio 12/B

Canine Parainfluenza type 2 virus, strain CPiV-2 Bio 15

Minimum

$10^{3.1}$ TCID₅₀

$10^{3.6}$ TCID₅₀

$10^{4.3}$ TCID₅₀

$10^{3.1}$ TCID₅₀

Maximum

$10^{5.1}$ TCID₅₀

$10^{5.3}$ TCID₅₀

$10^{6.6}$ TCID₅₀

$10^{5.1}$ TCID₅₀

Suspension (inactivated)

Leptospira interrogans serogroup Icterohaemorrhagiae

serovar Icterohaemorrhagiae, strain MSLB 1089

GMT \geq 1:51 ALR

Leptospira interrogans serogroup Canicola

serovar Canicola, strain MSLB 1090

GMT \geq 1:51 ALR

Leptospira kirschneri serogroup Grippotyphosa

serovar Grippotyphosa, strain MSLB 1091

GMT \geq 1:40 ALR

Leptospira interrogans serogroup Australis

serovar Bratislava, strain MSLB 1088

GMT \geq 1:51 ALR

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)

Read the package leaflet before use.

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/L4 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

Not applicable

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/L4 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 and *L.i.* serogroup Australis serovar Bratislava

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

sc

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.