SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel Pi/L4, lyophilisate and suspension for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substances:

Lyophilisate (live attenuated):	**Minimum**	**Maximum**
Canine Parainfluenza Type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ $TCID_{50}$*	$10^{5.1}$ $TCID_{50}$*
Suspension (inactivated):		
Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain MSLB 1089		GMT**≥1:51 ALR***
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090		GMT**≥1:51 ALR***
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091		GMT**≥1:40 ALR***
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088		GMT**≥1:51 ALR***
Adjuvant:		
Aluminium hydroxide (quantifies as Al_2O_3)		1.8-2.2 mg

* Tissue culture infectious dose – 50%
** Geometric mean titre
*** Antibody micro agglutination-lytic reaction (serology in rabbits)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

The visual appearance is as follows:
Lyophilisate: Spongy matter, white colour.
Suspension: Whitish liquid with easily shakeable sediments.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Active immunization of dogs from 6 weeks of age.

- to prevent clinical signs (nasal and ocular discharge) and reduce viral excretion caused by canine parainfluenza virus
- to prevent clinical signs, infection and urinary excretion caused by *L. interrogans* serogroup Australis serovar Bratislava
- to prevent clinical signs and urinary excretion and reduce infection caused by *L. interrogans* serogroup Canicola serovar Canicola and *L. interrogans* serogourp Icterhaemorhagiae serovar Icterohaemorrhagiae
- to prevent clinical signs and reduce infection and urinary excretion caused by *L. kirschneri* serogroup Grippotyphosa serovar Grippotyphosa

Onset of immunity:
- 3 weeks after completion of the basic vaccination for CPiV and
- 4 weeks after completion of the basic vaccination for *Leptospira* components.

Duration of immunity:
At least one year following the primary vaccination course for all components of Biocan Novel Pi/L4.

4.3 Contraindications
Do not use in case of hypersensitivity to the adjuvant or to any of the excipients.

4.4 Special warning for each target species
.
Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:

The live virus vaccine strain CPiV may be shed by vaccinated dogs but due to the low pathogenicity of the strain, it is not necessary to keep vaccinated dogs separated from non-vaccinated dogs.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
Following subcutaneous administration in dogs, a small transient swelling (up to 5 cm) may commonly be observed at the injection site, these can occasionally be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination.
In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.
As with any vaccine rare, occasional hypersensitivity reactions may occur. If such reaction occurs, appropriate treatment should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore, the use is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Dose and route of administration:
Aseptically reconstitute the lyophilisate with the suspension. Shake well and administer immediately the entire content (1 ml) of the reconstituted product.

Reconstituted vaccine: whitish or yellowish colour with slight opalescence.

Basic vaccination scheme:
Two doses of Biocan Novel Pi/L4 3-4 weeks apart from 6 weeks of age.

Revaccination scheme:
A single dose of Biocan Novel Pi/L4 to be given annually.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other adverse effects other than those mentioned under section 4.6 (Adverse reactions) have been observed after administration of an overdose of the vaccine. In minority of animal's pain was observed at the injection site immediately after administration of a 10x overdose of the lyophilized component. The pain lasted up to 1 minute and subsided without requiring any therapy.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Immunologicals for canidae, live viral and inactivated bacterial vaccines.

ATCvet code:
QI07AI08

The vaccine is intended for the active immunisation of healthy puppies and dogs against diseases caused by canine parainfluenza virus, *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, *Leptospira interrogans* serogroup Canicola serovar Canicola, *Leptospira interrogans* serogroup Australis serovar Bratislava, *Leptospira kirschneri* serogroup Grippotyphosa serovar Grippotyphosa.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Trometamol
Edetic acid
Sucrose
Dextran 70

Suspension:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Water for injection
Aluminium hydroxide

6.2 Major incompatibilities
Do not mix with any other veterinary medicinal product.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: administer the vaccine immediately.

6.4 Special precautions for storage
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging
The vaccine is supplied in Type I glass vials complying with Ph. Eur. Vials of the lyophilisate are closed with a bromobutyl rubber stopper and aluminium cap. Vials of the suspension are closed with a chlorobutyl rubber stopper and aluminium cap. The vaccine is supplied in transparent plastic boxes containing 10, 25 or 50 vials with 1 dose of lyophilisate and 10, 25 or 50 vials with 1 ml (1 dose) of suspension. The approved package insert is enclosed. Not all pack size may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.