PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Biocan Novel Puppy

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Bioveta, a. s., Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel Puppy, lyophilisate and solvent for suspension for injection for dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One vaccination dose (1 ml) contains:

Active substances
Lyophilisate

	Minimum	**Maximum**
Canine Distemper virus, strain CDV Bio 11/A, live attenuated	$10^{4,1}$ $TCID_{50}$	$10^{5,5}$ $TCID_{50}$
Canine Parvovirus type 2b, strain CPV-2b Bio 12/B, live attenuated	$10^{5,5}$ $TCID_{50}$	$10^{7,0}$ $TCID_{50}$

* Tissue culture infectious dose – 50%

Solvent
Water for injection 1 ml

The appearance before reconstitution:
Lyophilisate: Spongy matter, white colour.
Solvent: Clear colourless liquid.

4. INDICATION(S)

Active immunization of dogs from 6 weeks of age:
- to prevent mortality and clinical signs caused by canine distemper virus
- to prevent clinical signs, leukopenia and viral excretion caused by canine parvovirus type 2a, 2b and 2c

Onset of immunity:
Immunity against CDV and CPV is developed within 14 days after a single dose in puppies free of maternally derived antibodies.

Duration of immunity:
The duration of immunity against CDV and CPV in puppies without maternally derived antibodies was after a single dose of Biocan Novel Puppy vaccine determined for 12 months. The duration of immunity against CDV and CPV type 2b was demonstrated serologically and by challenge, duration of immunity against CPV types 2a and 2c was demonstrated serologically.

5. CONTRAINDICATIONS

Do not use in clinically diseased animals.

6. ADVERSE REACTIONS

Not observed.
As with other vaccines, hypersensitivity reactions may occur very rarely. If such a reaction, it is necessary to immediately provide appropriate treatment.

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

The recommended vaccination schedule

Basic vaccination scheme:
A single dose of Biocan Novel Puppy vaccine from 6 weeks of age.
In case where the presence of maternally derived antibodies against CDV and CPV is expected and if protection against other antigens is required a single dose of Biocan Novel Puppy vaccine should be followed by vaccination with polyvalent Biocan Novel vaccines that also contain CDV and CPV in accordance with the relevant SPC three weeks after vaccination with Biocan Novel Puppy.

Revaccination:
Annual revaccination with single dose of Biocan Novel Puppy vaccine should be given in cases that immunization against CDV and CPV is only required.
It is recommended that dogs, who received one dose of Biocan Novel Puppy followed by vaccination with polyvalent Biocan Novel vaccines that also contain CDV and CPV in accordance with the relevant SPC three weeks after vaccination with Biocan Novel Puppy, should be revaccinated with canine distemper virus and canine parvovirus by polyvalent Biocan Novel vaccines every 3 years in accordance with the relevant SPC.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute one vial of the lyophilisate (component CDV and CPV) aseptically using the solvent (water for injection). Shake well and immediately inject the entire content (1 ml) of the reconstituted vial.
Reconstituted vaccine: Clear colourless to yellowish liquid with light opalescence.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Only clinically healthy animals should be vaccinated.

The live virus vaccine strain CPV-2b can be spread to non-vaccinated animals but does not cause disease.

Since the vaccine virus strain CPV-2b has not been tested in domestic cats and other carnivores (except dogs) that are known to be susceptible to canine parvoviruses, it is recommended vaccinated dogs to be separated from other canine and feline species after vaccination.

Special warnings for each target species:
Immunological responses to the CDV and CPV components may be delayed due to maternally derived antibody interference. In situations where very high maternally derived antibodies levels against CDV and CPV are expected, the vaccination with further doses of polyvalent Biocan Novel vaccines that also contain CDV and CPV should follow.

Pregnancy, lactation:
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.

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.

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.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The vaccine is supplied in quantities of 5x1, 10x1 and 25x1 ml vials of each fraction (i.e. lyophilisate and solvent) in transparent plastic cartons.
Not all pack sizes may be marketed.