

Biocan Novel Respi nasal drops, lyophilisate and solvent for suspension for dogs

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,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocan Novel Respi nasal drops,
lyophilisate and solvent for suspension for
dogs

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

Each dose of 0,5 ml contains:

Active substances:

Live attenuated *Bordetella bronchiseptica*
strain MSLB 3096 $10^{6.0} - 10^{8.5}$ CFU*
Live attenuated Canine parainfluenza Type
2 virus, strain CPiV-2 Bio 15
 $10^{3.5} - 10^{5.8}$ CCID₅₀**

*CFU: Colony forming unit
**CCID₅₀: Cell culture infectious dose
50%

Solvent:

Water for injections (WFI) 0,5 ml

Lyophilisate: spongy matter of whitish
to yellowish colour.

Solvent: clear colourless liquid.

4. INDICATION(S)

Active immunisation of dogs from 3 weeks
of age:

- to reduce clinical signs and bacterial
excretion after infection with *Bordetella
bronchiseptica* and
- to reduce clinical signs and viral excretion
after infection with canine parainfluenza
virus.

Onset of immunity:

3 days after primary vaccination for
Bordetella bronchiseptica.

7 days after primary vaccination for canine
parainfluenza virus.

Duration of immunity: 1 year.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient mild nasal discharge is very
commonly, mild ocular discharge and mild
depression are commonly and mild
sneezing is uncommonly observed in
animals after vaccination. These signs
generally subside without treatment within
one to three days. Mild to moderate
coughing was commonly observed in
vaccinated kennel dogs from nine days
after vaccination when housed together
with non-vaccinated dogs.

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).
- If you notice any side effects, even those
not already listed in this package leaflet or
you think that the medicine has not worked,
please inform your veterinary surgeon.
Alternatively, you can report via your
national reporting system. For details
regarding the national system please
contact NCA.

7. TARGET SPECIES

Dogs.

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

Nasal use.

Dosage of administration:

Primary vaccination scheme:

A single dose from 3 weeks of age.

Re-vaccination scheme:

A single dose to be given annually.

9. ADVICE ON CORRECT ADMINISTRATION

Aseptically reconstitute the lyophilisate with
the solvent. Shake well after reconstitution.
Withdraw the liquid with the syringe,
remove the needle and administer directly
from the tip of the syringe into one nostril.
Alternatively, an intranasal applicator
(available separately) can be attached to
the syringe and the dose then administered
into one nostril. The vaccine should then be
used immediately.

The head of the dog should be held with
the nose pointing upwards. Administer one
dose (0,5 ml) of the reconstituted vaccine
into one nostril.

Reconstituted vaccine: whitish to yellowish
colour with a slight opalescence.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated

(2 °C – 8 °C).

Do not freeze.

Protect from light.

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

Use immediately after reconstitution.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

This product contains a live attenuated
bacterial strain and antibiotics may interfere
with the vaccine's efficacy. Therefore,
vaccinated animals should not receive
antibiotic treatment. If antibiotics are used
within one week after vaccination,
vaccination against *Bordetella
bronchiseptica* should be repeated e. g.
with a Bb monovalent vaccine (if available)
after completion of the antibiotic treatment.

Special precautions for use in animals:

After vaccination dogs may excrete the
vaccine strain *Bordetella bronchiseptica* for
up to 11 weeks after vaccination and the
vaccine strain canine parainfluenza virus
for 8 days. Unvaccinated dogs can manifest
mild clinical signs such as sneezing and
nasal and ocular discharge after contact
with vaccinated dogs.

The transmission of vaccine strains to cats,
pigs and rodents could not be
demonstrated. However, as the possibility
of transmission to non-target species
cannot be rejected, it is recommended to
keep non-vaccinated animals out of close
contact with vaccinated dogs for at least 4
weeks.

Safe handling and proper administration of
the vaccine and disposal of used material
contribute to eliminating the risk of
spreading the vaccine antigens in the
veterinary workplace.

Special precautions to be taken by the
person administering the veterinary
medicinal product to animals:

Hands and tools should be disinfected after
use.

In case of accidental self-administration
during dilution of the product or inhalation
of the product in the form of aerosol during
administration into the nostril of a dog, seek
medical advice immediately and show the
package leaflet or label to the physician.
Although the risk that immunocompromised
people are infected with *Bordetella
bronchiseptica* is extremely low, it should
be borne in mind that dogs can excrete the
bacteria for up to several weeks after
vaccination. Immunocompromised persons
are advised to avoid contact with the
vaccine and vaccinated dogs during
excretion.

Pregnancy and 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:

This product has been shown safe in dogs
from 8 weeks of age when given at the
same time as vaccines of the Versican

Dimensions (mm): A5 (148 × 210 mm) duplex printing
Colours: black
Prepared by: Doleželová
Date: 19.11. 2020

Approved by:

Date:

Plus/Biocan Novel and Vanguard ranges containing live canine parvovirus, adenovirus, distemper virus, parainfluenza virus as well as inactivated *Leptospira* and rabies virus. Mild (< 1 °C), transient increases in temperature were very commonly observed following co-administration of these vaccines.

Efficacy after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

Although proven safe it should not be necessary to give a parainfluenza vaccine twice by two different routes, therefore the veterinarian should consider vaccination options based on local availability of core vaccines without parainfluenza and monovalent Bordetella vaccines.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

Overdose (symptoms, emergency procedures, antidotes):

No other adverse reactions other than those mentioned under "Adverse reactions" were observed after administration of a 10-fold overdose of the vaccine.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2020

15. OTHER INFORMATION

Transparent plastic box containing 5 vials of lyophilisate (one dose) and 5 vials of solvent (0,5 ml).

Transparent plastic box containing 10 vials of lyophilisate (one dose) and 10 vials of solvent (0,5 ml).

Not all pack sizes may be marketed.

Applicators are packed separately and can be distributed together with the vaccine on request.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Only for animals.

The veterinary medicinal product is available only on prescription.

