ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

TRANSPARENT PLASTIC BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus BbPi IN nasal drops, lyophilisate and solvent for suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.5 ml contains:

Active substances:

Bordetella bronchiseptica	$10^{8.0}$ – $10^{9.8}$ CFU
Canine parainfluenza Type 2 virus	$10^{3.5}$ – $10^{5.8}$ $CCID_{50}$

3. PHARMACEUTICAL FORM

Nasal drops, lyophilisate and solvent for suspension

4. PACKAGE SIZE

5 x 1 dose
10 x 1 dose

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4210

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (1 dose lyophilisate)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus BbPi IN lyophilisate for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Pi, Bb (Biocan only)

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

IN (Biocan only)

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (0.5 ml solvent)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus BbPi IN solvent for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Aqua ad iniectabilia

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

0.5 ml

4. ROUTE(S) OF ADMINISTRATION

IN (Biocan only)

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Versican Plus BbPi IN 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:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Bioveta, a.s.,
Komenského 212,
683 23 Ivanovice na Hané,
CZECH REPUBLIC

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus BbPi IN 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
$10^{8.0}$ – $10^{9.8}$ CFU*

Live attenuated Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15
$10^{3.5}$ – $10^{5.8}$ $CCID_{50}$**

* CFU: Colony forming unit
** $CCID_{50}$: 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 kenneled 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 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 ºC), 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.

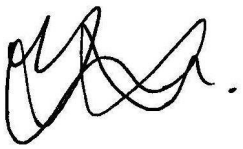
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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.



Approved: 27 April 2020