Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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%

Excipients:

Solvent:
Water for injections (WFI) 0.5 ml

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal drops, lyophilisate and solvent for suspension.

Lyophilisate: spongy matter of whitish to yellowish colour.
Solvent: clear colourless liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

After vaccination dogs may excrete the vaccine strain *Bordetella bronchiseptica* for up to 11 weeks 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.

4.6 Adverse reactions (frequency and seriousness)

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).

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 interactions

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 °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.

4.9 Amounts to be administered and administration route

Nasal use.

Dosage and route of 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.

Primary vaccination scheme:
A single dose from 3 weeks of age.

Re-vaccination scheme:
A single dose to be given annually.

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

No other adverse reactions other than those mentioned in section 4.6 were observed after administration of a 10-fold overdose of the vaccine.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, live bacterial and live viral vaccine.
ATCvet code: QI07AF01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Glucose
Sucrose
Dextran 40
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate

Solvent:
Water for injections

6.2 Major incompatibilities

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

Type I glass vial containing 1 dose of lyophilisate closed with a bromobutyl rubber stopper and aluminium cap.
Type 1 glass vial containing 0.5 ml of solvent closed with a chlorobutyl rubber stopper and aluminium cap.

Pack sizes:
Transparent plastic box containing 5 vials of lyophilisate (1 dose) and 5 vials of solvent (0.5ml).
Transparent plastic box containing 10 vials of lyophilisate (1 dose) and 10 vials of solvent (0.5ml).

Not all pack sizes may be marketed.

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

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
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Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/098/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2020

10 DATE OF REVISION OF THE TEXT