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:

Qualitative composition of excipients and other constituents
Lyophilisate:
Glucose
Sucrose
Dextran 40
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Solvent:
Water for injections (*Aqua ad iniectabilia*)

The visual appearance is as follows:
Lyophilisate: spongy matter of whitish to yellowish colour.
Solvent: clear colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

This veterinary medicinal product contains a live attenuated bacterial strain and antibiotics may interfere with the veterinary medicinal product's efficacy. Therefore, vaccinated dogs 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product 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 veterinary medicinal product or inhalation of the veterinary medicinal product in the form of aerosol during administration into the nostril of a dog, seek medical advice immediately and show the package leaflet or the 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 veterinary medicinal product and vaccinated dogs during excretion.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Nasal discharge[1]
Common (1 to 10 animals / 100 animals treated):	Ocular discharge[1] Cough[2] Depression[1]
Uncommon (1 to 10 animals / 1,000 animals treated):	Sneezing[1]

[1]Mild and generally subside without treatment within 1 to 3 days.
[2]Mild to moderate and observed in vaccinated dogs within 48 hours to one week after vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product when used with any other veterinary medicinal product except the products mentioned above. A decision to use this veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

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 veterinary medicinal product 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 veterinary medicinal product into one nostril.

Appearance of the reconstituted vaccine: whitish to yellowish colour with light opalescence.

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

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the veterinary medicinal product.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AF01

Live vaccine stimulating active immunity against *Bordetella bronchiseptica* and canine parainfluenza virus in dogs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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 I 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 veterinary medicinal product on request.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/098/001

8. DATE OF FIRST AUTHORISATION

25/08/2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/01/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).