SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Bb Oral lyophilisate and solvent for oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Lyophilisate:
Live attenuated *Bordetella bronchiseptica*, strain 92B: 1.4 x 10^8 - 5.5 x 10^9 CFU*/dose
*CFU: colony forming unit.

Excipients:

Qualitative composition of excipients and other constituents
Lyophilised fraction:
Bacto peptone
Sucrose
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide
Gelatin
MEM HEPES medium
Hydrochloric acid for pH adjustment
Sodium hydroxide for pH adjustment
Solvent:
Purified water

The visual appearance is as follows:
Lyophilisate: uniform off-white colour freeze-dried powder.
Solvent: clear colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For active immunisation of dogs of 8 weeks of age or older to reduce clinical signs following infection with *Bordetella bronchiseptica.*

Onset of immunity: 7 days.
Duration of immunity: 1 year.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The veterinary medicinal product contains live bacteria and must be administered by the oral route only. Parenteral administration can generate abscesses and cellulitis.

Vaccinated dogs may excrete the vaccine strain of *Bordetella bronchiseptica* for up to 35 days oronasally and for at least 70 days in faeces following vaccination.

Due to the attenuated nature of the vaccine strain it is not necessary to keep unvaccinated dogs separate from vaccinated dogs. However, during this time, it is advised that immunocompromised dogs avoid contact with vaccinated dogs.

The *Bordetella bronchiseptica* in the veterinary medicinal product has been shown to be safe in pigs exposed to the vaccine strain (e.g. from contact with vaccinated dogs). Cats exposed to the vaccine strain (e.g. from contact with vaccinated dogs) may show moderate clinical signs such as sneezing, nasal and ocular discharge.

Safety of the bacteria in the veterinary medicinal product shed by vaccinated dogs has not been studied in other animal species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Disinfect hands and equipment after use.

In case of accidental self-injection during reconstitution of the veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician.

Persons administering the veterinary medicinal product to the dog should be aware that repeated exposure to the veterinary medicinal product may lead to rare hypersensitivity reactions.

Immunocompromised persons are advised to avoid contact with the veterinary medicinal product and vaccinated dogs during the oronasal shedding period.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Ocular discharge[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea[2], Vomiting[2] Hypersensitivity reaction (e.g. anaphylaxis, dyspnoea and/or tachypnoea, facial oedema, urticaria)[3] Nasal discharge[2], Cough[2] Lethargy[2]

[1]Mild.
[2]Mild, for up to 14 days after vaccination.
[3]If a hypersensitivity reaction occurs; appropriate treatment should be administered without delay.

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 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, use is not recommended in pregnant or lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use immunosuppressive agents within 1 month of vaccination with the veterinary medicinal product.

Do not administer antibiotics for 14 days following vaccination.

The veterinary medicinal product has been shown safe when given at the same time as vaccines of the Versican Plus and Vanguard ranges containing live canine parvovirus, adenovirus, distemper virus, parainfluenza virus as well as inactivated *Leptospira* and rabies. Efficacy after concurrent use has not been tested.

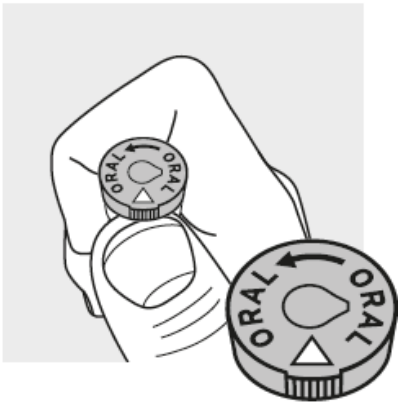
No information is available on the safety and efficacy of this veterinary medicinal product when used with any other veterinary medicinal product. A decision to use this veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Oral use.

Method and route of administration:

Grip the lyophilisate vial with your fingers and position your thumb directly under the embossed triangle on the vial cap.



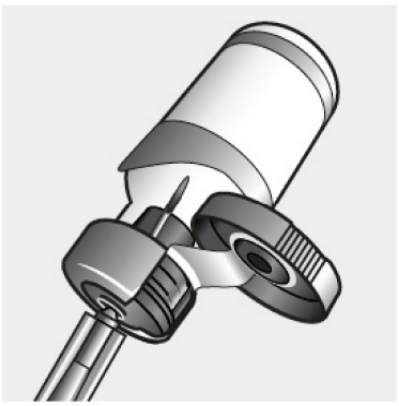
Using your thumb, push the vial cap upwards from underneath the embossed triangle to allow access to the rubber stopper.

Do not remove the vial cap or aluminium collar as they are not designed to be removed for use with a syringe and needle.

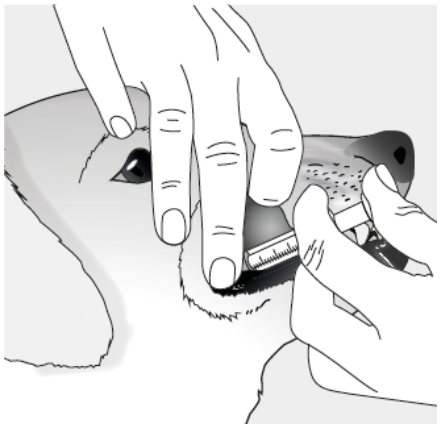
Aseptically reconstitute the lyophilisate with the solvent. The reconstituted veterinary medicinal product should be an orange to yellow turbid liquid which might contain a loose resuspendable sediment.

Shake the veterinary medicinal product well after reconstitution.

Withdraw the liquid with the syringe and remove the needle. The veterinary medicinal product should then be used immediately.



The head of the dog should be held with the nose pointing upwards and mouth open. Administer the entire 1 ml dose into the buccal pouch (between the teeth and the buccal mucosa).



Primary vaccination scheme:
Vaccination with 1 dose of 1 ml per dog from the age of 8 weeks.

Re-vaccination scheme:
One dose annually.

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

No adverse reactions other than those mentioned in section 3.6, were observed after a ten-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: QI07AE01

Live vaccine stimulating active immunity against *Bordetella bronchiseptica* in dogs.

A significant reduction of bacterial excretion following infection with *Bordetella bronchiseptica* was demonstrated from 3 weeks post-vaccination with a duration of immunity of 1 year.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the 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

Lyophilisate:
Vial: type I glass vial.
Closure: chlorobutyl rubber stopper sealed with aluminium collar and a coloured plastic cap.

Solvent:
Vial: type I glass vial.
Closure: chlorobutyl stopper sealed with aluminium collar and a coloured plastic cap.

Pack sizes:
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of 1 ml of solvent.
Plastic box containing 10 vials of 1 dose of lyophilisate and 10 vials of 1 ml of solvent.
Plastic box containing 25 vials of 1 dose of lyophilisate and 25 vials of 1 ml of solvent.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5119

8. DATE OF FIRST AUTHORISATION

21 August 2019

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 13 March 2026