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

Excipient:

Solvent:
Purified water 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for oral suspension.

Lyophilisate: Uniform off-white colour freeze-dried powder.

Solvent: clear colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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

Onset of immunity: 3 weeks
Duration of immunity: 12 months

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

The product contains live bacteria and must be administered by the oral route only. Parenteral administration can generate abscesses and cellulitis.

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

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

The *Bordetella bronchiseptica* in the vaccine 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 vaccine 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 product, seek medical advice immediately and show the package leaflet or the label to the physician.

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

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

4.6 Adverse reactions (frequency and seriousness)

Rarely a mild ocular discharge may occur after vaccination.

Very rarely mild transient diarrhoea, vomiting, nasal discharge, mild transient cough or lethargy can occur for up to 14 days after vaccination.

If an animal were to show more severe respiratory signs, appropriate treatment may be indicated.

Hypersensitivity reactions may occur in very rare cases. If such a reaction occurs, appropriate treatment should be administered without delay.

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 10animals 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, use is not recommended in pregnant or lactating bitches.

4.8 Interaction with other medicinal products and other forms of interaction

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

Do not administer antibiotics for 14 days following vaccination.

The 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 vaccine when used with any other veterinary medicinal product. 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

Oral use.

The vaccine is to be administered by oral route to dogs 8 weeks of age and older.

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.

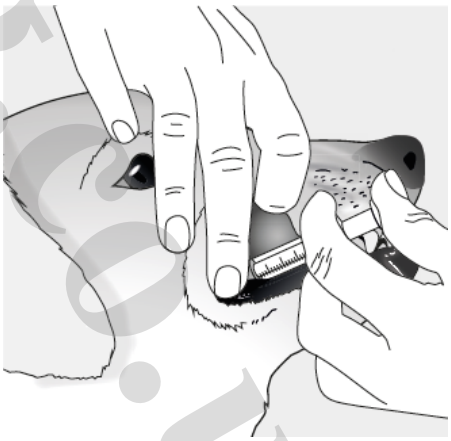
Using your thumb, push the vial cap upwards from underneath the embossed triangle to allow access to the rubber stopper.

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 product should be an orange to yellow coloured liquid.

Shake the product well after reconstitution. Withdraw the liquid with the syringe and remove the needle. The vaccine 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:
Vaccination with 1 dose of 1 ml per dog from the age of 8 weeks.

Re-vaccination:
One dose annually.

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

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

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae - live bacterial vaccines for dogs
ATC-vet code : QI07AE01

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. 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

2. Solvent:
   Purified water

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the 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). Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Vial: Type I glass vial
Closure: Chlorobutyl rubber stopper sealed with aluminum collar and a coloured plastic cap

Solvent:
Vial: Type I glass vial
Closure: Chlorobutyl stopper sealed with aluminum 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4209

DATE OF FIRST AUTHORISATION

21 August 2019

9. DATE OF REVISION OF THE TEXT

December 2020

Approved 03 December 2020