SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bronchi-Shield, Lyophilisate and Solvent for Suspension for Nasal Drops for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (1 ml) of vaccine contains:

1. Lyophilisate:

Active substance:
Live attenuated Bordetella bronchiseptica, strain 92B 2.1 x 10^6 to 5.5 x 10^8 CFU *
* CFU: colony forming unit

Excipients:
For the full list of excipients, see section 6.1.

2. Solvent:
Water for injections 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for for nasal drops, suspension for dogs.
Uniform cream colour freeze-dried powder.

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 coughing caused by Bordetella bronchiseptica.

Onset of immunity: from 5 days after vaccination.
Duration of immunity: 1 year.

4.3 Contraindications

Do not vaccinate animals undergoing antibacterial or immunosuppressive treatment. See section 4.6.

4.4 Special warnings for each target species

The product contains live bacteria and must be administered by the nasal route only. Parenteral administration can generate abscesses and cellulitis.
If any antibiotic is used within 2 weeks after vaccination, vaccination should be repeated after completion of the antibiotic treatment.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate healthy animals only.
Vaccinated dogs may excrete the vaccine strain of *Bordetella bronchiseptica* up to 7 weeks following vaccination. During this time, immunodepressed persons are advised to avoid contact with vaccinated dogs. Similar precautions are also applicable to unvaccinated in-contact or immunodepressed animals.
The vaccine has been shown safe in pigs. Cats and unvaccinated dogs in contact with vaccinated dogs may react to the vaccine strain, presenting moderate clinical signs such as sneezing, nasal and ocular discharge. Other animals, such as rabbits and small rodents, have not been tested.
Special precautions should be taken to avoid spreading of the vaccine strain in the clinic.

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 or inhalation of the aerosolized product at the time of application in the dog nostrils, 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 by inhalation of aerosolized product may lead to rare hypersensitivity reactions.
Although the risk that immunocompromised humans become infected with *Bordetella bronchiseptica* is extremely low, such individuals should be aware that dogs can shed the organism for up to 7 weeks after vaccination. Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated dogs during the shedding period.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, transient coughing (1 or 2 days) may occur during the first days following vaccination.
In rare cases, transient nasal or ocular discharge may be observed.

In animals, which show more severe signs, appropriate antibiotic treatment may be indicated. However, veterinarians should be aware that antibiotic treatment given less than 14 days after vaccination may impair vaccine efficacy.

Hypersensitivity reactions may occur in very rare cases. In case of anaphylactic reaction, administer adrenaline.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The use is not recommended during pregnancy and lactation due to the lack of supportive studies and possible spread of the vaccine strain.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use immunodepressing agents within 1 month of vaccination with the product.
Do not administer antibiotics during 14 days following vaccination.
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

Nasal use.
The vaccine is to be administered by drops to dogs of the age of 8 weeks and older.

Aseptically reconstitute the lyophilisate with the solvent.
Shake the product well after reconstitution. Withdraw the liquid with the syringe, remove the needle and replace with the applicator. The vaccine should be used immediately.
The head of the dog should be held with the nose pointing upwards and its mouth closed, so that it is forced to breathe through its nostrils. Administer the product in the nostrils drop by drop.

<u>Primary vaccination:</u>
Vaccination with 1 dose of 1 ml per dog from the age of 8 weeks.
Administer 0.5 ml of the vaccine in each nostril. For larger animals (>15 kg), 1 ml may be administered in a single nostril.
One dose at least five days before the period of anticipated risk, e.g. temporary kennelling.
See also section 4.5 “Special precautions for use”.
<u>Booster:</u>
Annual booster vaccination of one dose.

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

In addition to the adverse reactions mentioned in section 4.6, ten-fold overdose vaccinated puppies may sneeze one or more times following vaccination.

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:
   Peptone
   Sucrose
   Dipotassium phosphate
   Potassium dihydrogen phosphate
   Sodium hydroxide
   Gelatin
   Eagle HEPES medium
   Hydrochloric acid for pH adjustment
   Sodium hydroxide for pH adjustment

2. Solvent:
   Water for injections

6.2 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: Bromobutyl rubber stopper sealed with aluminum cap

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

Pack sizes:
Box containing 10 vials of 1 dose of lyophilisate and 10 vials of 1 dose of solvent and 10 cannulae for application

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 AUTHORIZATION HOLDER

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

8. MARKETING AUTHORIZATION NUMBER

Vm 42058/4011

9. DATE OF FIRST AUTHORISATION

18 July 2005

10. DATE OF REVISION OF THE TEXT

10 January 2020

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

Subject to prescription.

The manufacture, import, possession, sale, supply and/or use of Versican Plus Bb IN may be prohibited in a Member State on the whole or part of their territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and/or use Versican Plus Bb IN must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

Approved 10 January 2020