PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 x 1 dose fix-a-form label

Note that 10 x 1 dose fix-a-form labels contain the full text of the package insert. The text below is from the cover leaf only.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live attenuated *Bordetella bronchiseptica*, strain 92B: 2.1 x 10^6 to 5.5 x 10^8 CFU/ml per dose

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for nasal drops, suspension for dogs.

4. PACKAGE SIZE

10 x 1 dose. 10 vials of solvent and 10 cannulae for application

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not vaccinate pregnant or lactating bitches.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted: use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14 THE WORDS "KEEP OUT OF THE SIGHTAND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4011

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (1 ml) of vaccine contains:

Active substance:

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

Nasal use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Water for injections

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

Nasal use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burnait 1
Louvain-la-Neuve
1348, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Versican Plus Bb IN is a combination vaccine presented as a lyophilisate and solvent for nasal drops, suspension for dogs.
One dose (1 ml) of vaccine contains:1. *Lyophilisate*:
Active substance:

Live attenuated *Bordetella bronchiseptica*, strain 92B: 2.1×10^6 to 5.5×10^8 CFU*
*CFU: colony forming unitUniform cream colour freeze-dried powder.

2. *Solvent*:
Water for injections 1ml

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not vaccinate animals undergoing antibacterial or immunosuppressive treatment.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Nasal use.

Primary vaccination:
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.

Booster:
Annual booster vaccination of one dose.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the vial.

Shelf-life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The product contains live bacteria and must be administered by the intranasal 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.

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.

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

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.

Overdose (symptoms, emergency procedures, antidotes):
In addition to the adverse reactions mentioned in section “Adverse reactions”, ten-fold overdose vaccinated puppies may sneeze one or more times following vaccination.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:

Boxs containing 10 vials of 1 dose of lyophilisate and 10 vials of 1 dose of solvent and 10 cannulae for application.
Not all pack sizes may be marketed.

LEGAL CATEGORY

To be supplied only on veterinary 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 its 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.

MARKETING AUTHORISATION NUMBER

Vm 42058/4011

Approved 10 January 2020