ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box containing 5, 10 or 25 x 1 dose with outer booklet label or single label (depending on pack size and country)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Live attenuated *Bordetella bronchiseptica*, strain 92B: 1.4 x 10^8 - 5.5 x 10^9 CFU/ dose

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for oral suspension

4. PACKAGE SIZE

5 x 1 dose
10 x 1 dose
25 x 1 dose

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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. SPECIFIC 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(S)

Vm 42058/4209

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

Peel open label for more information (booklet label only).

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Bb Oral lyophilisate for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bb

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {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

Versican Plus Bb Oral solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Purified water

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Versican Plus Bb Oral lyophilisate and solvent for oral suspension 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 Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each dose of 1 ml contains:

Active substance:

Lyophilisate:
Live attenuated *Bordetella bronchiseptica*, strain 92B: 1.4×10^8 - 5.5×10^9 CFU*/dose

*CFU: colony forming unit

Uniform off-white colour freeze-dried powder.

Excipient:

Solvent
Purified water 1 ml

Clear colourless liquid

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Oral use.

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

Re-vaccination:
One dose annually.

9. ADVICE ON CORRECT ADMINISTRATION

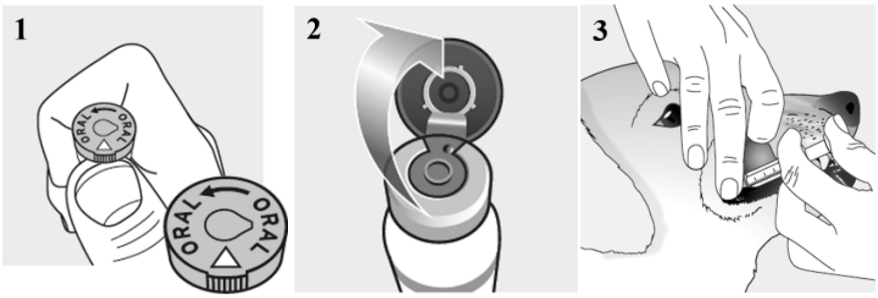
Method and route of administration:

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

2. 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.

3. 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).



[*if there are significant space concerns for the printed multilingual leaflet, please delete the illustrations and instructions from this section and relocate them to the end of the leaflet text. Add the following sentence in this section: "Please refer to the illustrations at the end of the leaflet for advice on correct administration."*]

10. WITHDRAWAL PERIOD(S)

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:

Vaccinate healthy animals only.

Special warnings 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 immunocompromised dogs 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.

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

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 range 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.

Overdose (symptoms, emergency procedures, antidotes):

No adverse reactions other than those mentioned in section 6, were observed after a ten-fold overdose of the vaccine.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Pack sizes:
Plastic box containing either 5, 10 or 25 vials of 1 dose lyophilizate and the same vial quantity of 1 ml of solution.

Not all pack sizes may be marketed

LEGAL CATEGORY

POM-V

MARKETING AUTHORISATION NUMBERS

42058/4209

Approved 03 December 2020