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.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

5 x 1 dose

10 x 1 dose

25 x 1 dose

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5119

15. BATCH NUMBER

Lot {number}

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

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LYOPHILISATE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versican Plus Bb Oral

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bb

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use immediately.

5. ROUTE(S) OF ADMINISTRATION

Oral use

6. 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

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Purified water

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

Oral use

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each dose of 1 ml contains:

Active substance:

Lyophilisate:

Live attenuated *Bordetella bronchiseptica*, strain 92B: $1.4 \times 10^8 – 5.5 \times 10^9$ CFU*/dose

*CFU: colony forming unit.

Excipient:

Solvent:

Purified water 1 ml

The visual appearance is as follows:

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

Solvent: clear colourless liquid.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:

Vaccinate healthy animals only.

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.

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 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.

Overdose:

No adverse events other than those mentioned in section “Adverse events”, were observed after a ten-fold overdose of the veterinary medicinal product.

Major incompatibilities:

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

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Oral use.

Primary vaccination scheme:

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

Re-vaccination scheme:

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.

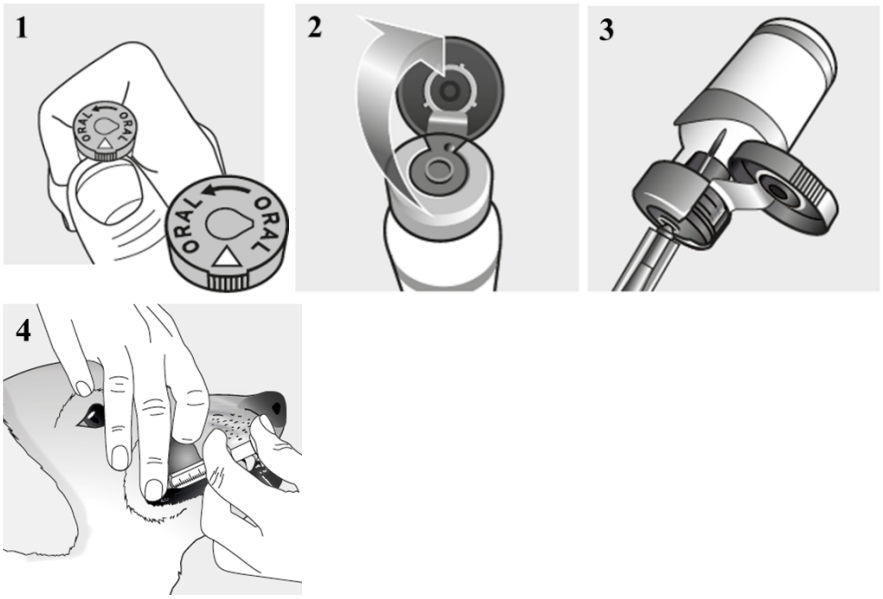
2. Using your thumb, push the vial cap upwards from underneath the embossed triangle to allow access to the rubber stopper.

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 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.

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

4. 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 PERIODS

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 after Exp.

The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

42058/5119

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

UK

Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:

Zoetis Belgium

Rue Laid Burniat 1

1348 Louvain-La-Neuve

Belgium

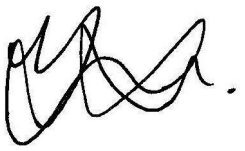
17. OTHER INFORMATION

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.

POM-V Veterinary medicinal product subject to prescription

For animal treatment only.



Approved: 28 February 2024