LABELLING AND PACKAGE LEAFLET

MULTIDOSE VIAL

A. LABELLING

MULTIDOSE VIAL

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX containing a multidose vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Bb suspension for injection for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains *Bordetella bronchiseptica* fimbriae: 88 - 399 U.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.
Shake well 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 broached, use within 4 weeks.
Date of broach:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Once broached, store between 2 °C – 25 °C and use within 4 weeks.
Store in the original package in order to 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor
Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Suffolk
IP30 9UP

16. MARKETING AUTHORISATION NUMBER

Vm 01708/5063

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL on multidose vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Bb 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

B. bronchiseptica fimbriae 88 - 399 U/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

Once broached, use within 4 weeks.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

MULTI-DOSE VIAL

PACKAGE LEAFLET:
Canigen Bb suspension for injection 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:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Bb suspension for injection for dogs

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

Each dose (1 ml) contains:

Active substance:
Bordetella bronchiseptica fimbriae[1]: 88 - 399 U[2]

[1] Purified from strain Bb7 92932
[2] Antigenic mass ELISA units

Adjuvant:
dl-α-tocopheryl acetate: 74.7 mg

Excipient:
Thiomersal: 0.15 mg

Aqueous, white to nearly white suspension, mild creaming.

4. INDICATION(S)

For active immunisation of dogs against *Bordetella bronchiseptica* to reduce clinical signs of upper respiratory tract disease and bacterial shedding post infection.

Onset of immunity: 2 weeks.

Duration of immunity: 7 months after primary vaccination.
1 year after re-vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient swelling at the site of injection (≤ 2 cm), which can occasionally be firm, may very commonly be present for up to 25 days post-vaccination. A medium size transient swelling at the site of injection (≤ 3.5 cm) may occur in common cases and can be painful. The swelling may uncommonly last for up to 35 days post-vaccination.

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 10 animals 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

Subcutaneous use, 1 ml dose per vaccination.
Dogs can be vaccinated from the age of 6 weeks onwards.

Primary vaccination:
Two vaccinations with an interval of 4 weeks.

Re-vaccination:
A single vaccination, administered 7 months after primary vaccination with this vaccine, is sufficient to maintain protection against *Bordetella bronchiseptica* for a further year. Thereafter, a single vaccination should be administered, annually. In case re-vaccination at 7 months is missed, a single vaccination within 12 months after primary vaccination is sufficient to extend protection against *Bordetella bronchiseptica* for a further year.

This vaccine can also be used for re-vaccination in a schedule where Canigen KC has been used for primary vaccination. A single vaccination, administered one year after primary vaccination with Canigen KC, is sufficient to prolong immunity against *Bordetella bronchiseptica* for another year.

Re-vaccination after primary vaccination with Canigen KC:
One vaccination, annually.

For associated use:
When this vaccine is administered in associated use (i.e. not mixed) with another vaccine of the Canigen series as indicated under section “Special Warnings”, the vaccines should be given subcutaneously at the same time, at a different site. Dogs should not be younger than the minimum age recommended for the other Canigen vaccine, as stated in the respective product information.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach room temperature (15 °C – 25 °C) before use.

Shake well before each administered dose. Avoid introduction of contamination by using a clean needle for each administered dose.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Once broached store between 2 °C – 25 °C. Do not freeze.
Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after ‘EXP’. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Pregnancy and lactation:
Can be used during pregnancy. The safety of this vaccine has not been investigated during the first 20 days of gestation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this Canigen Bb vaccine can be administered at the same time but not mixed with the live vaccines of the Canigen series against canine distemper, canine contagious hepatitis caused by canine adenovirus type 1, canine parvovirus disease and respiratory disease caused by canine adenovirus type 2, where authorized.

Safety data are available which demonstrate that this Canigen Bb vaccine can be administered at the same time but not mixed with the Canigen series of vaccines mentioned above together with the live Canigen parainfluenza vaccine and the inactivated vaccines of the Canigen series against leptospirosis caused by *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, *L. interrogans* serogroup Australis serovar Bratislava, and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Lianguang.
In addition, for the live canine parainfluenza vaccine antibody response data, and for the inactivated canine leptospirosis vaccines antibody response data and other immunity data support the use of the Canigen Bb vaccine at the same time but not mixed with the mentioned Canigen series of vaccines.

When this vaccine is administered in association with the relevant Canigen vaccines, the demonstrated safety and efficacy claims of Canigen Bb are the same as when this vaccine is administered alone.

The product information of the relevant Canigen vaccines used in association with this vaccine should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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):
Not applicable.

Incompatibilities:
Do not mix with any other 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

For animal treatment only.

Pack size:
Cardboard box with 1 multidose vial containing 10 doses (10 ml) of vaccine.

MA number: Vm 01708/5063

POM-V To be supplied only on veterinary prescription.

Distributor
Virbac Ltd.
Woolpit Business Park
Windmill Avenue, Woolpit
Bury St. Edmunds
Suffolk
IP30 9UP

Approved 16 November 2021