PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box (labelling information on inlay, front label and back label, with package leaflet attached to inlay)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen KC

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (0.4 ml) contains at least:
live *Bordetella bronchiseptica* bacteria strain B-C2 ≥ $10^{8.0}$ and ≤ $10^{9.7}$cfu
live *Canine parainfluenza virus* strain Cornell. ≥ $10^{3.0}$ and ≤ $10^{5.8}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Suspension for nasal administration

4. PACKAGE SIZE

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

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Canine Kennel Cough Vaccine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intranasal administration

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

SECTIONS 10 – 16 ARE PRINTED ON THE SEAL

10. EXPIRY DATE

EXP end of: {month/year}
Once reconstituted use within 1 hour.

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

Read package leaflet before use.

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

[Distribution category]

For animal treatment only.
POM-V
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

MA 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 01708/4492

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen KC

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.4 ml:
Bordetella bronchiseptica strain B-C2. ≥ $10^{8.0}$ cfu
Canine parainfluenza virus strain Cornell ≥ $10^{3.0}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension
Suspension for nasal administration.

4. PACKAGE SIZE

1 x 1 dose vaccine + 1 x diluent
5 x 1 dose vaccine + 5 x diluent
10 x 1 dose vaccine + 10 x diluent
25 x 1 dose vaccine + 25 x diluent
50 x 1 dose vaccine + 50 x diluent
1x 5 dose vaccine + 1 x 5 dose diluent
5 x 5 dose vaccine + 5 x 5 dose diluent
10 x 5 dose vaccine + 10 x 5 dose diluent
25 x 5 dose vaccine + 25 x 5 dose diluent
50 x 5 dose vaccine + 50 x 5 dose diluent
1x 10 dose vaccine + 1 x 10 dose diluent
5 x 10 dose vaccine + 5 x 10 dose diluent
10 x 10 dose vaccine + 10 x 10 dose diluent
25 x 10 dose vaccine + 25 x 10 dose diluent
50 x 10 dose vaccine + 50 x 10 dose diluent

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For active immunisation of dogs against *Bordetella bronchiseptica* and *canine parainfluenza virus* for periods of increased risk.
Canine Kennel Cough Vaccine

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nasal administration.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

Expiry end of: {month/year}
Once reconstituted used within 1 hour.

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2 °C - 8 °C.
Do not freeze.
Protect from light.
Keep the container in the outer package.
Allow the diluent to reach room temperature.

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

Read package leaflet before use.

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

[Distribution category]

For animal treatment only.
POM-V
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

MA 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 01708/4492

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Vaccine Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen KC

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

B. bronchiseptica ≥ $10^{8.0}$ cfu / dose
CPi ≥ $10^{3.0}$ $TCID_{50}$/ dose

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

1 dose
5 doses
10 doses

4. ROUTE(S) OF ADMINISTRATION

Intranasal

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Read package leaflet before use.
POM-V
Vm 01708/4492

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

1. NAME OF THE DILUENT

Canigen KC
Adjuvanted sterile diluent for the reconstitution of Canigen KC.

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose
5 doses
10 doses

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

5. BATCH NUMBER

Batch: {number}

6. EXPIRY DATE

Expiry end of: {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET FOR:
Canigen KC

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen KC
Lyophilisate and solvent for suspension for nasal administration.

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

After reconstitution in the solvent provided one dose (0.4 ml) contains:
live Bordetella bronchiseptica bacteria strain B-C2 ≥ $10^{8.0}$ and ≤ $10^{9.7}$cfu [1]
live Canine parainfluenza virus strain Cornell ≥ $10^{3.0}$ and ≤ $10^{5.8}$ $TCID_{50}$ [2]
[1]colony forming units
[2]Tissue Culture Infective Dose 50%

4. INDICATION(S)

Active immunisation of dogs against *Bordetella bronchiseptica* and *Canine parainfluenza virus* for periods of increased risk to reduce clinical signs induced by *B.bronchiseptica* and *Canine Parainfluenza virus* and to reduce shedding of *Canine Parainfluenza*.

Specific claims
Onset of immunity:
for *Bordetella bronchiseptica*: 72 hours after vaccination;
for *Canine parainfluenza virus*: three weeks after vaccination.
Duration of immunity: 1 year

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

Mild discharges from the eyes and nose can occur from the day after vaccination, sometimes accompanied by wheezing, sneezing and/or coughing particularly in very young susceptible puppies. Signs are generally transient, but in occasional cases may persist for up to four weeks. In animals, which show more severe signs, appropriate antibiotic treatment may be indicated. In very rare cases lethargy and vomiting may occur after vaccination. In very rare cases hypersensitivity reactions may occur. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening. If such reactions occur appropriate treatment is recommended. Clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia or immune-mediated polyarthritis have been reported in very rare cases.

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, not less than 3 weeks of age.

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

Dose: 0.4 ml
Administration: into one nostril

Vaccination scheme:
Dogs should be at least 3 weeks of age. When Canigen KC is concurrently administered (i.e. not mixed) with another Virbac vaccine as indicated in section (Interactions), dogs should not be younger than the minimum age recommended for the other Virbac vaccine.
Unvaccinated dogs should receive one dose at least 3 weeks prior to the period of anticipated risk, e.g. temporary kennelling in order to get protection for both vaccine agents. In order to get protection for *Bordetella bronchiseptica* unvaccinated dogs

should receive one dose at least 72 hours prior to the period of anticipated risk, e.g. temporary kennelling (see also section ‘Special precautions for use‘).
Revaccinate annually.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the sterile diluent provided to reach room temperature (15 °C - 25 °C). Aseptically reconstitute the freeze-dried vaccine with the diluent. Shake well after addition of the diluent. Remove the needle, and administer 0.4 ml into one nostril.

The contents of the vial should be used within 1 hour after reconstitution of the product.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at 2 °C - 8 °C.
Do not freeze.
Protect from light.
The vaccine should be transported under the recommended conditions.
Shelf-life after reconstitution according to directions: 1 hour.
Do not use after the expiry date stated on the label and carton.
Keep container in the outer packaging.

12. SPECIAL WARNING(S)

Only healthy dogs should be vaccinated. Cats, pigs and unvaccinated dogs may react to the vaccine strains with mild and transient respiratory signs. Other animals, like rabbits and small rodents have not been tested

Special precaution(s) for use in animals
Vaccinated animals can spread the *Bordetella bronchiseptica* vaccine strain for six weeks and the *Canine parainfluenza* vaccine strain for a few days after vaccination. It is therefore advisable to avoid close contact between immunocompromised humans and vaccinated animals during this period.

Special precautions to be taken by the person administering the product to animals
Immunocompromised individuals should avoid any contact with the vaccine and vaccinated dogs up to six weeks after vaccination.
Disinfect hands and equipment after use.

Interactions
Do not administer in conjunction with other intranasal treatments or during antibiotic treatment.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day, 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 authorised, and inactivated vaccines of the Canigen series against canine leptospirosis caused by all or some of the following serovars: *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/Liangguang. In very rare cases a transient acute hypersensitivity reaction may occur when this product is used with other vaccines.
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.
In case antibiotics are administered within one week after vaccination, the vaccination should be repeated after the antibiotic treatment is finished.
Do not mix with any other veterinary medicinal product.

Use during pregnancy
Can be used during pregnancy.

Overdose
Particularly in very young puppies, signs of upper respiratory tract disease may occur after an overdose, including ocular and nasal discharges, pharyngitis, sneezing and coughing. The signs may start the day after vaccination and have been seen for up to 4 weeks after vaccination.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

ATC code: QI07AF
The product contains live *Bordetella bronchiseptica* strain B-C2 and live *Canine parainfluenza virus* strain Cornell. After intranasal vaccination, the product stimulates the development of active immunity against *Bordetella bronchiseptica* and *Canine parainfluenza virus*.
No data on the influence of maternal antibodies on the effect of vaccination with Canigen KC are available. From literature, it is considered that this type of intranasal vaccine is able to induce an immune response without interference with maternally derived antibodies.
Data are available to show a reduction in shedding of *Bordetella bronchiseptica* from 3 months to 1 year after vaccination.

Pack sizes
Cardboard or plastic box with 10 or 50 glass vials containing equal amounts (5 + 5 or 25 + 25) of 1, 5 or 10 doses of the vaccine and 0.6, 2.4, 4.6 ml of the solvent.
Not all pack sizes may be marketed.

MA number: Vm 01708/4492

Legal category
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: 22/04/21