SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac KC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.4 ml vaccine reconstituted with diluent (water for injections):

Active substances:
$\geq 10^{8.0}$ and $\leq 10^{9.7}$cfu[1] of live *Bordetella bronchiseptica* bacteria strain B-C2
$\geq 10^{3.0}$ and $\leq 10^{5.8}$ $TCID_{50}$[2] of live canine parainfluenza virus strain Cornell

[1]colony forming units
[2]Tissue Culture Infective Dose 50%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for nasal administration

Lyophilisate: Off-white or cream-coloured pellet
Solvent: clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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 virus.

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

4.3 Contraindications

None

4.4 Special warnings

Only healthy dogs should be vaccinated.

4.5 Special precautions for use

Special precautions 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.
Immunosuppressive medication may impair the development of active immunity and may increase the chance of adverse effects caused by the live vaccine strains.
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 precautions to be taken by the person administering the veterinary medicinal 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy

4.8 Interaction with other medicinal products and other forms of interaction

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 Nobivac 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 Nobivac 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.

4.9 Amounts to be administered and administration route

Allow the sterile diluent provided to reach room temperature (15 - 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 directly from the tip of the syringe into one nostril.

Vaccination scheme:
Dogs should be at least 3 weeks of age. When Nobivac KC is concurrently administered (i.e. not mixed) with another vaccine of the Nobivac series as indicated under section 4.8, dogs should not be younger than the minimum age recommended for the other Nobivac 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 (see also section 4.5 Special precautions for use).
Revaccinate annually.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Not applicable

5. IMMUNOLOGICAL PROPERTIES

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 Nobivac 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.
ATCvet code: QI07AF

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin-based stabiliser.
Sodium chloride.
Phosphate buffer.
Water for injections.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except diluent recommended for use with the product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 27 months.
Shelf-life after reconstitution according to directions: 1 hour.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

3 ml (single dose presentation) or 10 ml (5 and 10 dose presentation) vial of glass Type I (Ph.Eur.) closed with a halogenobutyl rubber stopper and sealed

with coded aluminium cap and accompanied by a vial of sterile diluent.
The diluent supplied for reconstitution is filled in the same type container (glass Type I vial and rubber stopper) as the product. The filling volume is:
1 dose 0.6 ml
5 dose 2.4 ml
10 dose 4.6 ml

Pack sizes: Cardboard or plastic boxes with 1, 5, 10, 25 or 50 x 1, 5, or 10 doses of vaccine and diluent.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4631

9. DATE OF FIRST AUTHORISATION

15 November 1999

10. DATE OF REVISION OF THE TEXT

April 2021

Approved: 15/04/21