232569 R3

LIVE, FREEZE-DRIED VACCINE AGAINST *BORDETELLA BRONCHISEPTICA* AND CANINE PARAINFLUENZA VIRUS

Nobivac® KC

NOT FOR HUMAN USE; FOR ANIMAL TREATMENT ONLY

Warning: To be sold by retail on the prescription of a Veterinary Doctor only.

Nobivac® KC is a live freeze-dried vaccine containing live *Bordetella bronchiseptica* strain B-C2 and live Canine parainfluenza virus strain Cornell for active immunisation of dogs against *Bordetella bronchiseptica* and Canine parainfluenza virus, resulting in prevention of kennel cough.

Composition:
Each vial of one dose (0.4 ml) contains:

Active Ingredients	**Quantity**
Bordetella bronchiseptica strain B-C2	$\geq 10^{8.0}$ cfu
Canine parainfluenza virus strain Cornell	$\geq 10^{3.0}$ $TCID_{50}$
Stabiliser	
Hydrolysed gelatin	10 mg
NZ Amine	10 mg
Sorbitol	20 mg
Sodium Chloride	2mg
$Na_2H\ PO_4.2H_2O$	0.53mg
KH_2PO_4	0.05mg
Diluent	
Water for injection to	0.4ml

Target Species: Dogs

Indications:
Active immunisation of dogs against *Bordetella bronchiseptica* and Canine parainfluenza virus, resulting in prevention of Kennel cough disease.

Dose and administration:
Intranasal use.
Allow the sterile diluent provided to reach room temperature (15 °C – 25 °C). Aseptically reconstitute the lyophilisate with the diluent. Shake the vial well after addition of the diluent. Withdraw the vaccine into the syringe, 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 two weeks of age.
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

Revaccination: Annually.

Contraindications: None.

Special warnings:
Vaccinate healthy animals only.

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

The vaccine has been shown to be safe for use in pregnant bitches.

Vaccinated animals can spread the *Bordetella bronchiseptica* vaccine strain for six weeks and the canine parainfluenza vaccine strain for a few days after vaccination.

Efficacy and/or safety data are available which demonstrate that this vaccine can be administered on the same time but not mixed with Nobivac L4, Nobivac Lepto, Nobivac DHPPi, Nobivac DHP, Nobivac Puppy DP, Nobivac Puppy DP PLUS and Nobivac Parvo-C.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products stated 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 very rare cases a transient acute hypersensitivity reaction may occur when this product is used with other vaccines.
In case antibiotics are administered within one week after vaccination, the vaccination should be repeated after the antibiotic treatment is finished.

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Immunosuppressive medication may impair the development of active immunity and may increase the chance of adverse effects caused by the live vaccine strains.
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.

Special precautions for use:
Special precautions for safe use in the target species
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.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
None

Adverse events:
In laboratory studies and field trials:
Mild discharges from the eyes and nose has been observed very commonly 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 post marketing experience:
Lethargy and vomiting may occur after vaccination in very rare cases.
Hypersensitivity reactions may occur in very rare cases. 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.

Immunity:
Onset of immunity:
- for *Bordetella bronchiseptica*: 72 hours after vaccination
- for canine parainfluenza virus: three weeks after vaccination

Duration of immunity: 1 year

Interactions with other medicaments and forms of interaction:
Efficacy and/or safety data are available which demonstrate that this vaccine can be administered on the same time but not mixed with Nobivac L4, Nobivac Lepto, Nobivac DHPPi, Nobivac DHP, Nobivac Puppy DP, Nobivac Puppy DP PLUS and Nobivac Parvo- C.
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.

Withdrawal Period:
None

Symptoms of overdose (and where applicable, emergency procedures and antidotes): 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.

Precautions:
Allow the diluent to reach room temperature (+15 to +25°C). Shake well after addition of diluent. The contents of the vial should be used within 1 hour after reconstitution of the product.

List of excipients and other constituents:
Lyophilisate: hydrolysed gelatin, pancreatic digest of casein, sorbitol, sodium chloride,disodium phosphate dihydrate, potassium dihydrogen phosphate
Solvent: water for injections

Shelf life: Shelf life of the veterinary medicinal product: 27 months.
Shelf life after reconstitution: 1 hour.

Storage:
Vaccine and diluent should be stored between +2 °C and + 8 °C.
Keep out of reach of children.

Presentation:
1 dose vial

Manufactured by:
Intervet International B V
Wim de Körverstraat 35
5831 AN Boxmeer,
The Netherlands.

Imported and Marketed by:
Intervet India Pvt. Ltd.,
Bldg. No. B-1, Godown No.12 to 16,
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MSD Animal Health

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