SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac KC nasal drops, lyophilisate and solvent for suspension for dogs
Nobivac BbPi nasal drops, lyophilisate and solvent for suspension for dogs (AT, BE, DE, DK, LU, NO)
Nobivac KC vet. nasal drops, lyophilisate and solvent for suspension for dogs (SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.4 ml) of reconstituted vaccine contains:

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

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

Excipients:

Qualitative composition 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

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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: 3 weeks after vaccination.
Duration of immunity: 1 year.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated dogs may excrete the *Bordetella bronchiseptica* vaccine strain up to 6 weeks and the canine parainfluenza vaccine strain up to a few days following vaccination. During this time, the contact of immunosuppressed and unvaccinated dogs with vaccinated dogs should be avoided.
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 persons are advised to avoid contact with the vaccine and vaccinated animals up to 6 weeks after vaccination.
Disinfect hands and equipment after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Nasal discharge[1]. Ocular discharge[1].
Common (1 to 10 animals / 100 animals reacted):	Sneezing[1], cough[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Wheezing[1]. Lethargy. Vomiting. Hypersensitivity reaction, anaphylactic-type reaction[2]. Immune mediated haemolytic anaemia, immune mediated thrombocytopenia, immune mediated polyarthritis.

[1] Particularly observed in very young susceptible puppies. Signs are generally mild and 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.
[2] Such reaction may evolve to a more severe condition, which may be life-threatening. If such reaction occurs, appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 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 (based on strain 154) 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.

Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with the bivalent puppy vaccine of the Nobivac series that contains canine parvovirus strain 630a. Efficacy of this vaccine after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.

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.

3.9 Administration routes and dosage

Nasal use.

Allow the sterile solvent provided to reach room temperature (15 °C – 25 °C). Aseptically reconstitute the lyophilisate with the solvent. Shake the vial well after addition of the solvent. Withdraw the vaccine into the syringe, remove the needle and administer 0.4 ml directly from the tip of the syringe into one nostril.
The reconstituted vaccine is an off-white or yellowish coloured suspension.

<u>Vaccination scheme:</u>
Dogs should be at least 3 weeks of age. When this vaccine is concurrently administered (i.e. not mixed) with another vaccine of the Nobivac series as indicated in section 3.8, 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 3.5 'Special precautions for use').

Revaccinate annually.

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

Particularly in very young puppies, signs of upper respiratory tract disease have been observed after a 10-fold overdose of the vaccine, including ocular and nasal discharges, pharyngitis, sneezing and

coughing. The signs started the day after vaccination and have been seen for up to 4 weeks after vaccination.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI07AF01.

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 this vaccine 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial of 3 ml closed with a halogenobutyl rubber stopper and aluminium cap.

Solvent:
The solvent supplied for reconstitution is filled in the same type of container as the lyophilisate (type I glass vial with rubber stopper and aluminium cap). The filling volume is 0.6 ml.

Pack sizes:

Cardboard or plastic boxes with
- 5 x 1 dose of vaccine and solvent
- 25 x 1 dose of vaccine and solvent

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

{number}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD OR PLASTIC BOX containing vials of lyophilisate and solvent (1 dose presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac KC nasal drops, lyophilisate and solvent for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.4 ml) of reconstituted vaccine contains:
Live *Bordetella bronchiseptica* bacteria strain B-C2: $\geq 10^{8.0}$ and $\leq 10^{9.7}$ cfu
Live canine parainfluenza virus strain Cornell: $\geq 10^{3.0}$ and $\leq 10^{5.8}$ $TCID_{50}$

3. PACKAGE SIZE

5 x 1 dose
25 x 1 dose

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nasal use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 1 hour.

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

14. MARKETING AUTHORISATION NUMBERS

{number}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL – Lyophilisate (vial with 1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac KC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 1 hour.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL – Solvent (vial with 1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sterile Solvent
Water for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac KC nasal drops, lyophilisate and solvent for suspension for dogs

2. Composition

Each dose (0.4 ml) of reconstituted vaccine contains:

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

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

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

3. Target species

Dogs.

4. Indications for use

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: *Bordetella bronchiseptica*: 72 hours after vaccination;
Canine parainfluenza virus: 3 weeks after vaccination.
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:
Vaccinated dogs may excrete the *Bordetella bronchiseptica* vaccine strain up to 6 weeks and the canine parainfluenza vaccine strain up to a few days following vaccination. During this time, the contact of immunosuppressed and unvaccinated dogs with vaccinated dogs should be avoided.

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 persons are advised to avoid contact with the vaccine and vaccinated dogs up to 6 weeks after vaccination.

Disinfect hands and equipment after use.

Pregnancy:
Can be used during pregnancy.

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 (based on strain 154) 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.
Safety data are available which demonstrate that this vaccine can be administered on the same day but not mixed with the bivalent puppy vaccine of the Nobivac series that contains canine parvovirus strain 630a. Efficacy of this vaccine after concurrent use has not been tested. Therefore, while safety of concurrent use has been demonstrated, the veterinarian should take this into account when deciding to administer the products at the same time.
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.

Overdose:
Particularly in very young puppies, signs of upper respiratory tract disease have been observed after a 10-fold overdose of the vaccine, including ocular and nasal discharges, pharyngitis, sneezing and coughing. The signs started the day after vaccination and have been seen for up to 4 weeks after vaccination.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent recommended for use with the veterinary medicinal product.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Nasal discharge[1]. Ocular discharge[1].

Common (1 to 10 animals / 100 animals reacted):	Sneezing[1], cough[1].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Wheezing[1]. Lethargy. Vomiting. Hypersensitivity reaction, anaphylactic-type (allergic) reaction[2]. Immune mediated haemolytic anaemia (low amounts of red blood cells), immune mediated thrombocytopenia (decreased platelet count), immune mediated polyarthritis (inflammation of the joints).

[1] Particularly observed in very young susceptible puppies. Signs are generally mild and 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.

[2] Such reaction may evolve to a more severe condition, which may be life-threatening. If such 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 or the local representative of 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

Nasal use.
Administer one dose of 0.4 ml per animal.
Reconstitute 1 vial of vaccine with 1 vial of solvent.

Vaccination scheme:
Dogs should be at least 3 weeks of age. When this vaccine is concurrently administered (i.e. not mixed) with another vaccine of the Nobivac series as indicated in section 'Special warnings', 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 'Special warnings').

Revaccinate annually.

9. Advice on correct administration

Allow the sterile solvent provided to reach room temperature (15 °C – 25 °C). Aseptically reconstitute the lyophilisate with the solvent. Shake the vial well after addition of the solvent. Withdraw the vaccine into the syringe, remove the needle and administer 0.4 ml directly from the tip of the syringe into one nostril.
The reconstituted vaccine is an off-white or yellowish coloured suspension.

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

Shelf life after reconstitution according to directions: 1 hour.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{Number}

Pack sizes:
Cardboard or plastic boxes with
- 5 x 1 dose of vaccine and solvent
- 25 x 1 dose of vaccine and solvent

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information