1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Respira Bb suspension for injection for dogs
Nobivac Respira Bb vet. suspension for injection for dogs (DK, FI, IS, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.15 mg
Sodium chloride	
Disodium hydrogen phosphate dihydrate	
Sodium dihydrogen phosphate dihydrate	
Polysorbate 80	
Water for injections	

Aqueous, white to nearly white suspension, mild creaming.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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 revaccination.

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
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Dogs:

Very common (> 1 animal / 10 animals treated):	Injection site swelling (≤ 2 cm, occasionally firm, may be present up to 25 days post-vaccination)
Common (1 to 10 animals / 100 animals treated):	Injection site swelling (≤ 3.5 cm, may be present up to 25 days post-vaccination[1] and can be painful)
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[2]

[1] The swelling may uncommonly last for up to 35 days post-vaccination.
[2] If hypersensitivity reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered at the same time but not mixed with the live vaccines in the Nobivac range 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.

Safety data are available which demonstrate that this vaccine can be administered at the same time but not mixed with the Nobivac range of vaccines mentioned above together with the live Nobivac parainfluenza vaccine and the inactivated vaccines in the Nobivac range 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 there are antibody response data, and for the inactivated canine leptospirosis vaccines there are antibody response data and other immunity data which support the use of the vaccine at the same time but not mixed with the mentioned Nobivac range of vaccines.

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

The product information of the relevant Nobivac 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.

3.9 Administration routes and dosage

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

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.

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

Revaccination:
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 revaccination 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 revaccination in a schedule where Nobivac KC has been used for primary vaccination. A single vaccination, administered one year after primary vaccination with Nobivac KC, is sufficient to prolong immunity against *Bordetella bronchiseptica* for another year.

Revaccination after primary vaccination with Nobivac KC:
One vaccination, annually.

For associated use:
When this vaccine is administered in associated use (i.e. not mixed) with another vaccine in the Nobivac range as indicated under section 3.8, 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 Nobivac vaccine, as stated in the respective product information.

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

Not applicable.

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: QI07AB03.

The subunit vaccine stimulates active immunity against *Bordetella bronchiseptica* infection in dogs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 4 weeks.

5.3. Special precautions for storage

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.

5.4. Nature and composition of immediate packaging

Polyethylene terephthalate (PET) vial closed with a halogenobutyl rubber stopper and aluminium cap.

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

5.5. Special precautions for the disposal of unused veterinary medicinal product 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

{to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY} {to be completed nationally}.

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

{MM/YYYY} {to be completed nationally}

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