

SUMMARY OF PRODUCT CHARACTERISTICS

MULTIDOSE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:

Bordetella bronchiseptica fimbriae¹: 88 - 399 U²

¹ Purified from strain Bb7 92932

² Antigenic mass ELISA units

Adjuvant:

dl- α -tocopheryl acetate: 74.7 mg

Excipient:

Thiomersal: 0.15 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Aqueous, white to nearly white suspension, mild creaming.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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 re-vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling at the site of injection (≤ 2 cm), which can occasionally be firm, may very commonly be present for up to 25 days post-vaccination. A medium size transient swelling at the site of injection (≤ 3.5 cm) may occur in common cases and can be painful. The swelling may uncommonly last for up to 35 days post-vaccination.

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. The safety of this vaccine has not been investigated during the first 20 days of gestation.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this Nobivac Respira Bb vaccine can be administered at the same time 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 authorized.

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

When this vaccine is administered in association with the relevant Nobivac vaccines, the demonstrated safety and efficacy claims of Nobivac Respira Bb 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.

4.9 Amounts to be administered and administration route

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.

Re-vaccination:

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 re-vaccination 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 re-vaccination 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.

Re-vaccination 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 of the Nobivac series as indicated under section 4.8, 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.

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

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for canidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia)

ATCvet code: QI07AB03.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl- α -tocopheryl acetate
Thiomersal
Sodium chloride
Disodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Polysorbate 80
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 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.

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

{to be completed nationally}

8. MARKETING AUTHORISATION NUMBER(S)

{national number}

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

MULTIDOSE VIAL

A. LABELLING
MULTIDOSE VIAL

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX containing a multidose vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains *Bordetella bronchiseptica* fimbriae: 88 - 399 U.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.
Shake well before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 4 weeks.

Date of broach:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.

Once broached store between 2°C - 25°C and use within 4 weeks.

Store in the original package in order to protect from light.

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

Disposal: read package leaflet.

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

For animal treatment only. 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

{to be completed nationally}

16. MARKETING AUTHORISATION NUMBER(S)

{to be completed nationally}

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL on multidose vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Respira Bb
DK, FI, IS, NO, SE: Nobivac Respira Bb vet.



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

B. bronchiseptica fimbriae 88 - 399 U/ml

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once broached use within 4 weeks.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

MULTI-DOSE VIAL

PACKAGE LEAFLET:
Nobivac Respira Bb suspension for injection for dogs
DK, FI, IS, NO, SE: Nobivac Respira Bb vet. suspension for injection for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
{ to be completed nationally }

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each dose (1 ml) contains:

Active substance:

Bordetella bronchiseptica fimbriae¹: 88 - 399 U²

¹ Purified from strain Bb7 92932

² Antigenic mass ELISA units

Adjuvant:

dl- α -tocopheryl acetate: 74.7 mg

Excipient:

Thiomersal: 0.15 mg

Aqueous, white to nearly white suspension, mild creaming.

4. INDICATION(S)

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 re-vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient swelling at the site of injection (≤ 2 cm), which can occasionally be firm, may very commonly be present for up to 25 days post-vaccination. A medium size transient swelling at the site of injection (≤ 3.5 cm) may occur in common cases and can be painful. The swelling may uncommonly last for up to 35 days post-vaccination.

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.

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

Subcutaneous use, 1 ml dose per vaccination.

Dogs can be vaccinated from the age of 6 weeks onwards.

Primary vaccination:

Two vaccinations with an interval of 4 weeks.

Re-vaccination:

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 re-vaccination 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 re-vaccination 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.

Re-vaccination 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 of the Nobivac series as indicated under section "Special Warnings", 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this Nobivac Respira Bb vaccine can be administered at the same time 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 authorized.

Safety data are available which demonstrate that this Nobivac Respira Bb vaccine can be administered at the same time but not mixed with the Nobivac series of vaccines mentioned above together with the live Nobivac parainfluenza vaccine and the inactivated vaccines of the Nobivac series 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.

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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.

Overdose (symptoms, emergency procedures, antidotes):

Not applicable.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:

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