LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX containing single dose pre-filled syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Respira Bb suspension for injection in pre-filled syringe

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

5 x 1 ml and needles
10 x 1 ml and needles

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Store in the original package in order to 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

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3002

15. BATCH NUMBER

Lot {number}

Under Article 13 of EU Reg 2019/6 the following additional information is included:

Keep the syringes in the outer box.

Disposal: Read package leaflet.

To be supplied only on veterinary prescription.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL single dose pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Respira Bb

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

B. bronchiseptica fimbriae 88 - 399 U/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Under Article 13 of EU Reg 2019/6 the following additional information is included:

Suspension for injection in pre-filled syringe

SC

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac Respira Bb suspension for injection in pre-filled syringe for dogs

2. 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

Aqueous, white to nearly white suspension, mild creaming.

3. Target species

Dogs.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
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 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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	Hypersensitivity reaction.[2]

reports):	

[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 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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes 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.

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 “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 the correct administration

Allow the vaccine to reach room temperature (15 °C – 25 °C) before use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the syringes in the outer box.

Store in a refrigerator (2 °C – 8 °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 precautions for disposal

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:
Vm 01708/3002

Pack sizes:
Cardboard box with:
- 5 single dose pre-filled syringes (5 x 1 ml) and needles.
- 10 single dose pre-filled syringes (10 x 1 ml) and needles.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2022

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

17. Other information

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

Approved 02 March 2023