LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Box label:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb for Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.2 ml dose contains:
$10^{6.3}$ - $10^{8.3}$ CFU of live *Bordetella bronchiseptica* bacteria strain B-C2.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension.

4. PACKAGE SIZE

5 unit-dose vials of lyophilisate and 5 vials of solvent.

5. TARGET SPECIES

Cats

6. INDICATION

Live vaccine against feline upper respiratory tract disease caused by *Bordetella bronchiseptica*.

7. METHOD AND ROUTE OF ADMINISTRATION

For nasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use for special warnings for immunocompromised humans.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store at 2 – 8 °C.
Protect from light.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5046

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the vaccine vial:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

$10^{6.3}$ - $10^{8.3}$ CFU/dose *B. bronchiseptica*

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

1 dose.

4. ROUTE(S) OF ADMINISTRATION

Nasal use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for the solvent vial:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb for Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 dose

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

0.5 ml

4. ROUTE OF ADMINISTRATION

See package leaflet.

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR
Nobivac Bb lyophilisate and solvent for suspension for cats

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb lyophilisate and solvent for suspension for cats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each dose (0.2 ml) of reconstituted suspension contains:

Lyophilisate:
$10^{6.3}$ - $10^{8.3}$ colony forming units (CFU) of live *Bordetella bronchiseptica* strain B-C2

Solvent:
Water for injections

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

4. INDICATION(S)

For active immunisation of cats, of 1 month of age or older, to reduce clinical signs of *Bordetella bronchiseptica* associated with upper respiratory tract disease.

The onset of immunity was established in 8 week old cats as early as 72 hours after vaccination.

The duration of immunity is up to 1 year.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating queens.

6. ADVERSE REACTIONS

After administration, occasionally sneezing, coughing, mild and transient discharge from the eyes or nose may occur. After overdose, identical signs appear particularly in very young susceptible kittens. In cats that show more severe signs, appropriate antibiotic treatment may be indicated.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

One dose, of 0.2 ml of reconstituted vaccine at least 72 hours prior to period of anticipated risk.

For nasal use.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the solvent to reach room temperature. Aseptically reconstitute the freeze-dried vaccine with 0.3 ml of the sterile solvent provided. Shake well after addition of the solvent. Withdraw 0.2 ml of reconstituted vaccine into a 1 ml or 2 ml syringe, remove the needle and administer the whole contents of the syringe into one of the cat’s nostrils.

The head of the cat should be held with its nose pointing upward and its mouth closed, so that it is forced to breathe through its nostrils. Place the syringe in front of one of the nostrils and carefully administer the whole contents of the syringe into the nasal cavity via this nostril. The vaccine is administered directly from the tip of the syringe onto the opening of the nostril and enters the nasal cavity during inhalation.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store at 2 – 8 °C. Protect from light.
Do not use after the expiry date which is stated on the label.
Shelf-life after reconstitution according to directions: 4 hours.

12. SPECIAL WARNINGS

Only healthy cats should be vaccinated.

Sneezing by cats after administration does not adversely affect the efficacy of the veterinary medicinal product.

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

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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.

Do not administer during antibiotic treatment, or in conjunction with any other intranasal veterinary medicinal product.

If any antibiotic is administered within one week after vaccination, the vaccination should be repeated after the antibiotic treatment has been completed.

Vaccinated animals can spread the *Bordetella bronchiseptica* vaccine strain for six weeks; in individual cases for at least one year. Intermittent spreading is possible as well.

Although the risk of immunocompromised humans becoming infected with *Bordetella bronchiseptica* is extremely low, it is advised that cats that are in close contact with immunocompromised humans are not vaccinated with this vaccine. Such individuals should also be aware that cats can shed the organism for up to 1 year after vaccination.

Dogs, pigs and unvaccinated cats may react to the vaccine strain with mild and transient respiratory signs. Other animals, such as rabbits and small rodents, have not been tested.
Appropriate disinfection procedures should be used following use of this live bacterial vaccine.

In case of accidental self-administration seek medical advice immediately and show the package leaflet or the label to the physician.

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

Dispose of waste material that has had contact with the active substance by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

February 2022

15. OTHER INFORMATION

For animal treatment only.

Presentations:
Carton box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent
Plastic box containing 5 vials of 1 dose of lyophilisate and 5 vials of solvent

Not all presentations may be marketed.

Approved 18 February 2022