SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Bb for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.2 ml) of reconstituted suspension contains:

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

Solvent:
Water for injection

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension.

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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.

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

Duration of immunity: The duration of immunity is up to 1 year.

No data on the influence of maternal antibodies on the effect of vaccination with Nobivac Bb for cats are available. From literature it is considered that this type of

intranasal vaccine is able to induce an immune response without interference from maternally derived antibodies.

4.3 Contraindications

None known.

4.4 Special warnings

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

4.5 Special precautions for use

Special precautions for use in animals

Only healthy cats should be vaccinated.

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

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

Vaccinated animals can spread the vaccine strain of *Bordetella bronchiseptica* for six weeks, and there may be intermittent shedding for at least one year.

Although the risk of immunocompromised humans becoming infected with *Bordetella bronchiseptica* is extremely low, it is advised that cats which are in close contact with immunocompromised humans are not vaccinated with this vaccine.

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.

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

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

Appropriate disinfection procedures should be used following use of this live bacterial vaccine.

Although the risk that immunocompromised humans become infected with *Bordetella bronchiseptica* is extremely low, such individuals should be aware that cats can shed the organism for up to 1 year after vaccination.

4.6 Adverse reactions (frequency and seriousness)

After administration, occasionally sneezing, coughing, mild and transient discharge from the eyes or nose, may occur. In cats that show more severe signs, appropriate antibiotic treatment may be indicated.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating queens.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

Nasal use.

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

Allow the solvent to reach room temperature. Aseptically reconstitute the lyophilisate with 0.3 ml of the sterile solvent provided. Shake well.
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 upwards 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.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of an overdose of the vaccine.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Felidae* – cat - live bacterial vaccines.
ATCvet code: QI06AE02

To stimulate active immunity against *Bordetella bronchiseptica.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Gelatin
Sorbitol
Phosphate buffers

Solvent:
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after reconstitution: use within 4 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

One 3 ml unit-dose vial (glass Type I) of lyophilisate sealed with a halogenobutyl rubber stopper and an aluminium cap, supplied with a vial (glass Type I) of 0.5 ml sterile solvent sealed with a halogenobutyl rubber stopper.

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.

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

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.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5046

9. DATE OF FIRST AUTHORISATION

10 September 2002

10. DATE OF REVISION OF THE TEXT

February 2022

Approved 18 February 2022