European Medicines Agency
Veterinary Medicines

EMEA/V/C/068

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NOBIVAC BB

EPAR summary for the public

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Nobivac Bb?

Nobivac Bb is a vaccine that contains a live bacterium *Bordetella bronchiseptica* strain B-C2. Nobivac Bb is a dry substance and solvent that are made up into a suspension, which is given via the nose.

What is Nobivac Bb used for?

Nobivac Bb is used to vaccinate cats aged one month or older against the disease (a flu-like illness) caused by the bacterium *B. bronchiseptica*.
Cats are vaccinated by giving a 0.2-ml dose into one nostril. Immunity against infection is usually established after around three days and lasts for up to a year.

How does Nobivac Bb work?

Nobivac Bb is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Nobivac Bb contains a type of live *B. bronchiseptica* called strain B-C2. When a cat is given the vaccine, the immune system recognises the bacteria as 'foreign' and makes a special type of antibodies against them. In the future, the immune system will be able to produce these antibodies more quickly when it is again exposed to the bacteria. The live bacterium strain included in Nobivac Bb differs from other types of *B. bronchiseptica* because it is missing certain molecules and is therefore less likely to cause disease. This makes it suitable for use in a vaccine. Vaccines against *B. bronchiseptica* that are administered through the nose are also used in dogs.

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How has Nobivac Bb been studied?

The effectiveness of Nobivac Bb was investigated in three main studies involving cats of various breeds. The cats were vaccinated with Nobivac Bb before being challenged by being exposed to wild-type *B. bronchiseptica*. Nobivac Bb was the first live *B. bronchiseptica* vaccine licensed for use in cats.

What benefit has Nobivac Bb shown during the studies?

The main studies showed that Nobivac Bb was effective in reducing the symptoms caused by *B. bronchiseptica*.

What is the risk associated with Nobivac Bb?

Occasional side effects include sneezing, coughing and a mild and temporary discharge from the eyes or nose. In animals that show more severe signs, treatment with an antibiotic may be necessary.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The vaccine may be administered by veterinarians only. In case of accidental administration to people seek medical advice immediately and show the Package Leaflet or label to the doctor. Although the risk for people with weak immune systems becoming infected with *B. bronchiseptica* is extremely low, it is advised that cats which are in close contact with such people are not vaccinated with Nobivac Bb, since they can shed the bacteria intermittently for up to a year after vaccination.

Why has Nobivac Bb been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Nobivac Bb exceed the risks of its use. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Nobivac Bb:

The European Commission granted a marketing authorisation valid throughout the European Union for Nobivac Bb to Intervet International B.V. on 10 September 2002. The marketing authorisation was renewed on 25 September 2007. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 25 September 2007.