Veterinary Medicines Directorate

**United Kingdom**
**Veterinary Medicines Directorate**
**Woodham Lane**
**New Haw**
**Addlestone**
**Surrey KT15 3LS**

**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

## Canigen Bb Suspension for Injection in Pre-filled Syringe for Dogs

**Date Created:**
**December 2021**

# MODULE 1

## PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Canigen Bb Suspension for Injection in Pre-filled Syringe for Dogs |
| Applicant | MSD Animal Health UK Limited<br>Walton Manor<br>Walton<br>Milton Keynes<br>Buckinghamshire<br>MK7 7AJ |
| Active substance(s) | Bordetella bronchiseptica |
| ATC Vetcode | QI07AB03 |
| Target species | Dogs |
| Indication for use | For active immunisation of dogs against Bordetella bronchiseptica to reduce clinical signs of upper respiratory tract disease and bacterial shedding post infection.<br>Onset of immunity: 2 weeks.<br>Duration of immunity: 7 months after primary vaccination and 1 year after re-vaccination. |

# MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

# MODULE 3

## PUBLIC ASSESSMENT REPORT

| | |
|---|---|
| Legal basis of original application | Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended. |
| Date of conclusion of the procedure | 23/11/2021 |

## I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Nobivac Respira Bb Suspension for Injection in Pre-filled Syringe for Dogs.

## II. OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product is favourable.

# MODULE 4

## POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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