Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Canigen DP Lyophilisate and Solvent for Suspension for Injection for Dogs (Puppies)

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Canigen DP Lyophilisate and Solvent for Suspension for Injection for Dogs (Puppies)
Applicant	MSD Animal Health UK Limited Walton Manor Walton Milton Keynes Buckinghamshire MK7 7AJ
Active substance(s)	Live attenuated canine distemper virus strain Onderstepoort. Live recombinant canine parvovirus strain 630a.
ATC Vetcode	QI07AD03
Target species	Dogs
Indication for use	For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.

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 13(c) of Directive 2004/28/EC as amended.
Date of conclusion of the procedure	12/02/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Nobivac DP PLUS.

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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