Veterinary Medicines Directorate

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Post Authorisation Assessments

Canigen DHPPi Lyophilisate for Suspension for Injection for Dogs

Vm 01708/4519

•	18 April 2023	Update of the product information in relation to safety warnings after PSUR assessment. Alignment of the informed consent marketing authorisation's product information with that of the parent product.
•	13 September 2022	To introduce associated non-mixed use of Canigen DHPPi with Canigen Bb and to update SPC section 4.8 and Package Leaflet section 12 accordingly.
•	23 February 2022	Minor changes to an approved test procedure of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form.
•	28 April 2021	Change in the address of a manufacturer of an active substance.
•	05 November 2020	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	22 September 2017	Change in the SPC, labelling or package leaflet due to new data.
•	11 August 2016	Increase in batch size of active substance.
•	27 August 2015	Introduction of plastic boxes as secondary packaging in addition to the cardboard boxes already in use. Approval of revised mock-ups. Update of section 4.8 of SPC to expand on compatibility claim with the Canigen range containing Inac. Leptospira interrogans serogroup canicola strain Ca-12-000 and serogroup icterohaemorrhagiae, strain 820K and/or Inactivated Rabies virus strain Pasteur RIV.
•	05 September 2013	Change in name of manufacturer of the finished product
•	08 February 2013	Addition of a test procedure on the finished product Addition of a site for QC testing Addition of a site for manufacture of the finished product
•	15 December 2011	Change in batch size of the finished product
•	08 July 2010	Renewal
•	18 March 2009	Increase in batch size of the active substance Change of manufacturer of the finished product
•	15 January 2009	Deletion of a batch safety test
•	17 June 2008	Change of packaging material
•	09 April 2008	Change of test procedure performed on the finished product
•	04 July 2007	Addition of a manufacturer of active substances

•	01 June 2007	Submission of an updated Ph. Eur. Certificate of Suitability for an excipient
•	19 October 2006	Change of shelf life of two antigens – Parovirus antigen, from 24 to 36 months Parainfluenzavirus antigen, from 12 to 24 months
•	26 July 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	20 October 2005	Review
•	07 July 2005	Change to vaccination regime
•	27 April 2005	Renewal
•	14 January 2005	Addition of a manufacturer of an active substance
•	19 September 2003	Change to indications – extension of duration of immunity for canine distemper, hepatitis and canine parovirus to 2 years, and canine influenza to 1 year.
•	25 July 2003	Change of batch size
•	30 September 2002	Change of formulation Change of manufacturer, and manufacturer responsible for assembly for dosage form and packaging Change of address of distributor
•	23 June 2000	Change of name and address of MAH