Veterinary Medicines Directorate

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Post Authorisation Assessments

Canigen DHPPi Lyophilisate for Suspension for Injection for Dogs

Vm 06376/4107

19 December 2024	Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes Buckinghamshire, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands
04 July 2024	The registration dossiers of the concerned products are supplemented with (i) the information on the use of animal derived (porcine/bovine) trypsin in the manufacture of the hydrolysed gelatin and with (ii) respective extraneous agents and TSE risk assessments.
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