Veterinary Medicines Directorate

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Post Authorisation Assessments

Eurican DHPPi

Vm 08327/4126

•	24 October 2023	Update to the description of starting materials of biological origin.
•	18 August 2023	Extension of a storage period of the active substance supported by real time data.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	10 February 2023	The variation is to introduce the use of recombinant trypsin as a substitute to porcine trypsin for the manufacture of the active substance.
•	31 January 2023	Reduction of the minimum volume criterion of the CPV active ingredient for the formulation of lyophilisate.
•	26 January 2022	Changes in the manufacturing process of the active substance. Change of a test procedure for the active substance.
•	08 July 2021	Change in the batch size (including batch size range*) of the active substance used in the manufacturing process of the active substance. Change in storage conditions of the active substance. Change in the manufacturing process of the active substance.
•	09 April 2021	Changes to the labelling and package leaflet.
•	15 February 2021	Deletion of manufacturing site for the finished product.
•	22 July 2020	Change in the name of a manufacturer of the active substance.
•	18 June 2020	Change in the name of the manufacturer of the finished product.
•	27 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	16 December 2019	Change of a test procedure for the active substance.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	12 April 2018	Change of a test procedure for the finished product.
•	31 October 2017	Replacement of a test procedure for the active substance.
•	22 February 2017	Tightening of specification limits of the finished product.
•	02 December 2016	Change in the SPC, labelling or package leaflet due to new data.

•	17 June 2015	Submission of two TSE Ph. Eur. Certificates of suitability.
•	14 May 2014	Change in specification parameters and limits for the finished product.
•	30 October 2013	Change to manufacturing process of the active substance and finished product Change to test procedures performed on the finished product
•	23 May 2013	Update of specifications of the finished product
•	18 April 2013	Update of control tests performed on the finished product
•	30 May 2012	Removal of a manufacturing site of an active substance
•	09 May 2012	Update to sections 4.8, 4.9 and 6.2 of the SPC Removal of the diluent container from the pack
•	16 March 2011	Change of tests performed on an active substance Change of manufacturing process of the finished product Change of manufacturing process of an active substance
•	13 September 2010	Change in specification of the finished product
•	11 November 2009	Change in test procedure performed on the finished product
•	23 June 2009	Harmonisation of the SPC
•	24 October 2007	Change of manufacturer of active substance
•	15 August 2007	Update of EDQM certificates
•	26 July 2007	Deletion of a manufacturing site of an active substance
•	18 January 2007	Renewal
•	29 November 2006	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	10 February 2006	Submission of a new ph. Eur. Certificate of Suitability for an active substance from an already approved manufacturer
•	21 January 2005	Removal of a test performed on the finished product
•	05 September 2003	Renewal
•	28 March 2003	Addition of 4 manufacturers of starting materials used during the manufacture of the active substance
•	20 August 2002	Addition of a manufacturing site for manufacture of the dosage form, primary and secondary packaging
•	07 August 2002	Addition of a manufacturing site for filling and freeze drying
•	27 March 2002	Change of manufacturer of the active substance
•	26 February 2001	Addition of a manufacturer of the active substance
•	31 August 2000	Addition of a new manufacturing site for QC procedures
•	17 January 2000	Change of manufacturing process of the active substance
•	15 July 1998	Change of manufacturing process of the active substance Changes to specification of the active substance