Veterinary Medicines Directorate

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Post Authorisation Assessments

Eurican DAPPi Lyophilisate and Solvent for Suspension for Injection

Vm 08327/5024

•	12 June 2024	Change in the specification parameters in the SPC Section 6.5 Nature and composition of immediate packaging Immediate container: type I glass vials with chlorobutyl rubber stoppers, sealed with aluminium caps.
•	12 June 2024	Change in the presentation of the solvent. The aim of the variation is thus to update the product information of Eurican DAP and DAPPi to reflect this additional possibility for lyophilizates reconstitution with Eurican L4.
•	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.
•	15 March 2023	To reduce the minimum volume for the CPV active ingredient formulation in DAP and DAPPI lyophilisates.
•	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.
•	17 March 2022	Change of a test procedure for the active substance. Changes in the manufacturing process of the active substance.
•	21 January 2022	Deletion of a non-significant specification parameter of the finished product. Replacement to a test procedure for the finished product.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	16 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.
•	15 February 2021	Deletion of manufacturing site for the finished product.
•	04 February 2021	Renewal - UK as CMS.
•	26 November 2020	Change in the name of the manufacturer of 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.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	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 December 2016	Tightening of specification limits of the finished product.