Veterinary Medicines Directorate

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Post Authorisation Assessments

Duphalyte Solution for Injection

Vm 42058/4042

•	12 November 2020	Deletion of a supplier of packaging components or devices. Minor changes to an approved test procedure of the finished product. Deletion of a test procedure for the finished product. Deletion of a test procedure for the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Changes to a test procedure for the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions.
•	26 August 2020	Change in the address of the MAH from Zoetis UK Limited, 5th Floor, 6 St. Andrew Street, London. EC4A 3AE to Zoetis UK Limited 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey. KT22 7LP.
•	02 October 2017	To update SPC/QRD to reflect change of status of an active to excipient. To update SPC/QRD to reflect change of status of an active to excipient.
•	03 June 2014	Change in the name of manufacturer of the finished product (including batch release). Change of distributor. Change of MAH from Pfizer Limited to Zoetis UK Limited.
•	19 September 2012	Change of dimensions of the immediate packaging Change of supplier of an immediate packaging component
•	29 May 2012	Change in composition of a packaging component
•	19 January 2012	Changes to an existing pharmacovigilance system as

		described in the DDPS
•	06 July 2011	Change of name of a manufacturer and assembler of the dosage form
•	23 February 2010	Change of MAH
•	15 May 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	11 January 2007	Renewal
•	20 December 2005	Change of test method performed on and active substance
•	22 September 2005	Introduction of in use shelf life of 28 days