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Post Authorisation Assessments

Equip FT Vm 42058/4062

	05.14	
•	25 March 2024	Change in the source of a starting material used in the manufacturing process of the active substance.
•	28 September 2022	Change in name and address of a manufacturer of the
		active substance.
•	22 July 2022	Removal of the non-toxicity and in vivo residual toxicity test from in-process testing. Replacement of the absence of toxin and irreversibility of toxoid test with the absence of tetanus toxoid test performed on the purified toxoid bulk.
•	19 August 2020	Change in the address of the marketing authorisation holder 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.
•	09 April 2020	Changes to a test procedure for the finished product.
•	18 February 2020	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Changes in the manufacturing process of the active substance.
•	03 December 2019	Changes to a test procedure for the starting material.
•	15 November 2018	Deletion of manufacturing site for an active substance
•	26 October 2018	Changes to a test procedure for the active substance
•	27 June 2016	Deletion of a manufacturing site Change in the specification limits of the finished product
•	18 November 2015	Addition of a new presentation form
•	23 April 2013	Change of manufacturer of a starting material used in the manufacture of the active substance
•	13 December 2011	Addition of an administration device
•	14 November 2011	Renewal
•	14 September 2011	Change in manufacturing procedure of the finished product Change in test procedure performed on the finished product
•	30 December 2010	Change of name of manufacturer for the whole manufacturing process
•	01 July 2010	Addition of a manufacturing site for secondary packaging
•	29 June 2010	Addition of a manufacturing site for batch release
•	21 April 2009	Change of MAH
•	10 September 2008	Changes to test procedure performed on the finished product

•	21 August 2008	Harmonisation of SPC
•	15 August 2007	Replacement of an in-process test performed on the
		finished product
•	04 April 2007	Change of legal category from POM to POM-V
		Changes to the SPC and Product Literature to bring in
		line with new legislation