Veterinary Medicines Directorate

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Post Authorisation Assessments

Nobilis Erysipelas
Vm 01708/4546

•	16 December 2022	The maximum batch size of E. rhusiopathiae antigen to be increased from currently registered 2000 L to 3000 L. Update of blending of finished product to include addition of a fixed amount of hydrochloric acid. To add MSD AH Danube Biotech GmbH, Krems (KRE), Austria as an additional site for production of the E. rhusiopathiae antigen. 1. Add the possibility for aseptic addition of polysorbate-80 to the main fermenter medium prior to use as alternative for addition during medium preparation. 2. Add the possibility to use purified water as alternative for water for injections (WFI) to adjust the cell content of the antigen concentrate.
•	04 March 2021	Change in the composition (excipients) of the finished product. Change(s) in the manufacturing process of the active substance.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	02 June 2020	Change in the name of the MAH, from Intervet UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	13 November 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	09 November 2016	Changes to an existing pharmacovigilance system as described in the DDPS.
•	16 December 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	24 January 2014	Renewal.
•	22 March 2011	Deletion of a manufacturing site for the active substance.
•	22 March 2011	Change in name and address of a finished product manufacturer.
•	04 November 2010	Addition of a manufacturing site for part of the manufacturing process of the finished product.
•	23 June 2010	Changes to details in MAH pharmacovigilance system.