Veterinary Medicines Directorate

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Post Authorisation Assessments

Cobactan 25mg/ml Suspension for Injection

Vm 01708/4445

•	17 April 2023	Deletion of a microbiological testing site for the finished product.
•	22 November 2022	Change in address of a manufacturer of the active substance.
•	22 February 2022	Minor changes to an approved test procedure. Tightening on single impurity specification limits. Addition of new specification parameter for unidentified impurities. Addition of known impurities specifications to release specification.
•	21 December 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Changes to a test procedure for the finished product.
•	10 September 2021	Updates to the ASMF.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	04 June 2019	Change in the name of a manufacturer of the finished product
•	28 August 2018	Change in the specification limits of the finished product.
•	24 August 2016	Addition of a site where batch testing takes place.
•	07 January 2016	Harmonisation of the wording for the withdrawal periods, and approval of new mock ups.
•	07 March 2012	Changes to the SPC and product literature following an EU Directive.
•	07 September 2011	Change of manufacturer of the active substance.
•	31 August 2011	Change to the specification parameters for the finished product.
•	12 August 2011	Deletion of a manufacturing site.
•	24 March 2011	Change in specification of the finished product
•	11 November 2009	Minor change in the manufacturing process of the active substance
•	07 September 2009	Changes to finished product specification Change of test procedure performed on the active substance
•	12 May 2009	Addition of site of batch testing
•	14 October 2008	Change in test procedure performed on the finished product
•	12 August 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in

		line with new legislation
•	04 June 2008	Change of name of product from ‘Cephaguard’ to ‘Cobactan Cattle and Swine 2.5% Suspension for Injection’
•	09 August 2007	Renewal
•	10 June 2005	Change of distributor
•	20 July 2004	Addition of a manufacturing site for an intermediate involved in the manufacture of the active substance
•	16 May 2003	Renewal
•	17 October 2001	Change of manufacturing site of the dosage form
•	03 July 2001	Change of distributor
•	17 March 2000	Change of MAH
•	30 November 1999	Change of manufacturing site of the active substance
•	25 May 1999	Addition of target species – pigs