Veterinary Medicines Directorate

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Post Authorisation Assessments

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs

Vm 01708/4590

•	29 September 2023	Addition of a quality control site for the finished product.
•	21 June 2023	Change in the specification parameters or limits of the finished product: – addition of a new specification parameter to the specification with its corresponding test method.
•	23 March 2023	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	10 March 2022	Changes in the SPC & Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	04 September 2019	Update to the Active Substance Master File
•	14 November 2013	Change of address for a manufacturer. Change to the manufacturing process of the active substance, change to a test procedure for the active and change into the specification parameters for the active.
•	25 April 2013	Change in manufacturing process of the finished product
•	29 May 2012	Change of MAH Change of distributor Deletion of a manufacturer of the dosage form and site of assembly
•	03 August 2011	Change of components of the packaging
•	21 June 2011	Addition of a manufacturing site of the finished product Change of batch size change to manufacturing process of the finished product
•	12 January 2011	Change in test procedure performed on the finished product
•	15 December 2010	Change of specification of the active substance
•	22 September 2010	Addition of a manufacturer of the active substance
•	03 April 2008	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	09 July 2007	Renewal
•	08 August 2003	Renewal
•	02 June 2003	Deletion of target species – pigs and sheep Increase in withdrawal period for cattle from 4 to 19 days
•	12 January 1998	Renewal