

Post Authorisation Assessments

Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs Vm 06376/4127

03 January 2025	Change in legal entity of the Marketing Authorisation Holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, MK7 7AJ to Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, Netherlands.
10 July 2024	Change in the batch size of the finished product. Change in the manufacturing process of the finished product. Change in the specification limits of the finished product. Replacement or addition of a site where batch control/testing takes place. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
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