



Post Authorisation Assessments

Chorulon 1500 IU Powder and Solvent for Solution for Injection Vm 01708/4301

•	17 March 2023	Change in immediate packaging of the finished product.
•	11 October 2022	Substantial changes to an ASMF.
•	01 April 2021	Change in the name of the MAH from Intervet UK Limited to MSD Animal Health UK Limited.
•	20 November 2020	Change in the name of a manufacturer used in the manufacture of the active substance. Extension of the retest period for the intermediates used in the manufacture of the active substance.
•	12 June 2019	Change in the name of the manufacturer of the finished product.
•	18 September 2018	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	21 August 2017	Change in the specification limits of the finished product
•	20 September 2016	Change in the manufacturer of the active.
•	29 June 2015	Addition of a secondary packaging site. Changes in the manufacturing processes of the finished product. Change in immediate packaging of the finished product. Addition of a quality control and batch release site. Addition of a site for sterility testing. Addition of a manufacturing site for the manufacture of the finished product.
•	19 March 2015	Change in the re-test period of the active substance. Change in control of the active substance. Change in the supplier of the starting material and thus a change to the information for the manufacturing process

		of the active substance.
•	27 October 2014	Change to the name of the active substance manufacturer.
•	22 September 2011	Change in test procedure for the finished product.
•	24 August 2011	Update of Active Substance Master File (ASMF).
•	17 November 2010	Change of specification of the active substance.
•	03 April 2009	Change of name of a manufacturer of the active substance.
•	04 November 2008	Renewal.
•	06 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.
•	10 October 2007	Update to Part II of the Dossier.
•	14 September 2007	Change of name of the manufacturer of the active substance.
•	21 March 2007	Change of manufacturing site of the finished product.
•	20 June 2005	Change of distributor.
•	12 December 2003	Renewal.
•	27 July 2001	Change of distributor.
•	02 June 2000	Update of licence particulars.
•	13 March 1997	Change of dosage and administration details.
•	05 May 1995	Change of dosage and administration details.