



## Post Authorisation Assessments

### Chorulon 1500 IU Powder and Solvent for Solution for Injection Vm 06376/4090

|                   |  |
|-------------------|--|
| 04 February 2025  | Changes to the quality part of the dossier: Deletion of a manufacturing site for an active substance.  |
| 22 November 2024  | Change in legal entity of MA holder from MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ to Intervet International B.V., Wim de Körverstraat, 35, 5831 AN Boxmeer, The Netherlands.  |
| 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.<br>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.<br>Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>Addition of a new specification parameter to the specification with its corresponding test method of the finished product.<br>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.<br>Changes in the manufacturing processes of the finished product.<br>Change in immediate packaging of the finished product.<br>Addition of a quality control and batch release site.  |

|                   |  |
|-------------------|--|
|                   | Addition of a site for sterility testing.<br>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.<br>Change in control of the active substance.<br>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.<br>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.   |