Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Regumate Equine 2.2 mg/ml Oral Solution for Horses

Vm 06376/5038

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| 02 September 2026 | Deletion of pack sizes of the finished product. |
| 22 May 2026 | Change in the name and address of the manufacturer responsible for quality control testing of the finished product. |
| 10 April 2026 | Updated user warnings and adverse events table. |
| 14 March 2026 | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 25 March 2025 | Change in legal entity 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. |
| 20 February 2025 | One-off alignment of the product information with version 9.0* of the QRD templates. |
| 19 January 2025 | Minor changes to an approved test procedure for the finished product (NI). |
| 14 November 2024 | Minor changes to an approved test procedure for the finished product (GB). |
| 13 February 2024 | Change in the name of a manufacturer of the active substance.<br>Change in the name of a ASMF holder.<br>Change in the name of a ASMF holder. (NI) |
| 26 October 2022 | Change in the name of a manufacturer of the active substance.<br>Change in the name of a ASMF holder. |
| 13 August 2021 | Addition of a site where batch control/testing takes place.<br>Addition of a site where batch control/testing takes place. |
| 01 July 2021 | Minor change to an approved test procedure for the active substance/ starting material/ intermediate used in the manufacturing process of the active substance.<br>Tightening of specification limits of an active substance / starting material/ intermediate/ reagent used in the manufacturing process of the active substance.<br>Deletion of a non-significant parameter of an active substance/ starting material/ intermediate/ reagent used in the manufacturing process of the active substance.<br>Extension of a re-test period of the active substance.<br>Change in storage conditions of the active substance.<br>Changes to the approved specification limits for starting materials.<br>Minor change to the restricted part of an Active Substance Master File.<br>Minor change to the restricted part of an Active Substance Master File. |

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| 16 October 2020 | Change in the manufacturer of a starting material used in the manufacturing process of the active substance. |
| 14 August 2020 | Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited. |
| 31 July 2018 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. |
| 04 April 2018 | Minor change to an approved test procedure used in the manufacturing process of the active substance.<br>Change to an approved stability protocol.<br>Tightening of specification limits used in the manufacturing process of the active substance.<br>Minor change in the manufacturing process of the active substance.<br>Minor change to the restricted part of an Active Substance Master File.<br>Change in the manufacturer of a starting material used in the manufacturing process of the active. |
| 28 March 2017 | Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. |
| 31 October 2012 | Changes to the text on the labelling. |
| 29 August 2012 | Change to batch size of the intermediate in the manufacture of the active substance. |
| 22 February 2012 | Change of the withdrawal period for meat and offal. |
| 11 November 2011 | Change in the manufacturing process of the active substance. |
| 20 September 2010 | Registration of an alternative manufacturing process of the active substance. |
| 09 June 2010 | Change in the test procedure of the finished product. |
| 05 February 2010 | Renewal. |
| 08 June 2009 | Change to finished product specification. |
| 13 March 2009 | Addition of a supplier of the active substance. |
| 09 April 2008 | Change of legal category from POM to POM-V. |
| 10 December 2007 | Change of name of the active substance manufacturer. |
| 03 August 2007 | Change in storage conditions for the active substance. |
| 22 February 2007 | Change of batch size of finished product. |
| 01 August 2005 | Change in the distributor for Northern Ireland. |