Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Regumate Equine 2.2 mg/ml Oral Solution for Horses

Vm 06376/3040

02 September 2026	Deletion of pack sizes of the finished product.
09 July 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. Change in the name of a ASMF holder. Change in the name of a ASMF holder. (NI)
26 October 2022	Change in the name of a manufacturer of the active substance. Change in the name of a ASMF holder.
13 August 2021	Addition of a site where batch control/testing takes place. 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. Tightening of specification limits of an active substance / starting material/ intermediate/ reagent used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance/ starting material/ intermediate/ reagent used in the manufacturing process of the active substance. Extension of a re-test period of the active substance. Change in storage conditions of the active substance. Changes to the approved specification limits for starting materials. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File.

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. Change to an approved stability protocol. Tightening of specification limits used in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File. 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.