Veterinary Medicines Directorate

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

Post Authorisation Assessments

Regumate Porcine, 0.4% w/v Oral Solution

Vm 01708/4443

•	15 June 2022	Change in the name of a manufacturer of the active substance. Change in the name of an ASMF holder.
•	28 July 2021	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
•	02 July 2021	Change to the approved specification limit for a starting material.
•	12 March 2021	Change in the name of the marketing authorisation holder from Intervet UK Ltd to MSD Animal Health UK Limited.
•	10 February 2021	Minor change to an approved test procedure for the active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Tightening of specification limits of an active substance 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. Change to several manufacturing processes of the veterinary medicinal product. Minor change to the restricted part of an Active Substance Master File. Minor change to the restricted part of an Active Substance Master File.
•	17 September 2020	Change in the manufacturer of a starting material used in the manufacturing process of the active.
•	14 January 2020	Deletion of manufacturing site for a finished product.
•	01 November 2019	Deletion of an immediate packaging container.
•	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.
•	29 December 2016	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
•	06 January 2016	Variation to introduce an additional pack size
•	19 August 2015	Change to the in-use shelf-life of the 1 litre presentation, from 30 days to 90 days.
•	28 October 2014	Minor changes in test procedures for the active substance.
•	27 October 2014	Change to the name of the active substance manufacturer.
•	29 September 2014	Changes to test procedures for the finished product.
•	08 March 2013	Grouped variation to update the in-process controls by tightening existing in-process limits, the addition of a new in-process limit, and the deletion of an in-process limit.
•	19 June 2012	Variation to increase production batch size.
•	13 June 2012	Grouped variation to reduce the finished product shelf life.
•	22 February 2012	Variation to change the withdrawal period for meat and offal.
•	30 November 2011	Variation to change the distributor details.
•	16 November 2011	Addition of a warning statement on the labelling and package leaflet.
•	03 October 2011	Deletion of a site of secondary assembly.
•	31 August 2011	Variation concerning a minor change in the manufacturing process of the active substance.
•	02 August 2011	Deletion of a non-significant test parameter.
•	02 August 2011	Variation to make changes to the specification parameters used in the manufacturing process of the active substance.
•	02 August 2011	Variation to make changes to the specification parameters of materials used in the manufacturing process of the active substance.
•	02 June 2010	Variation to make a minor change to the manufacturing process of the active substance.
•	20 January 2010	Minor change to the composition of the finished product.
•	20 April 2009	Variation to change the address of a manufacturer (contract filling site).
•	26 November 2008	Change of distributor.
•	24 October 2008	Addition of a presentation with a different pack size and shape.
•	21 August 2008	Addition of an active substance manufacturer.
•	21 August 2007	Variation to change the name of the active substance manufacturer.
•	25 April 2007	Variation to change the storage conditions of the active substance.
•	14 December 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	22 February 2006	Change of test procedure for the active substance.
•	29 November 2005	Renewal.
•	19 October 2005	Extension of the withdrawal periods.
•	16 January 2004	Change to the supplier of the active substance.

•	10 April 2002	Renewal.
•	28 June 2001	Variation concerning the assembly site of dosage form.
•	28 June 2001	Variation concerning the assembly site of dosage form.
•	22 November 2000	Change of distributor.
•	17 March 2000	Change in the name and address of the Marketing Authorisation Holder. (including the manufacturer of active substance and dosage form).
•	08 April 1998	Renewal.
•	09 December 1996	Change of Marketing Authorisation Holder.