Veterinary Medicines Directorate

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Post Authorisation Assessments

GastroGard 370 mg/g Oral Paste

Vm 08327/3025

•	25 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	24 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	27 January 2023	Change in address of manufacturer of the finished product.
•	16 August 2022	Change in address of manufacturer of the finished product.
•	01 December 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	22 October 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	05 November 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	February 2019	Change in the name of the manufacturer of the finished product.
•	16 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Limited, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG, United Kingdom to Boehringer Ingelheim Animal Health UK Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.
•	13 November 2018	Changes to the labelling and package leaflet.
•	26 June 2018	Change in RMS from UK to IE.
•	21 June 2018	Change in the invented name of the veterinary medicinal product from GastroGard 37% w/w Oral Paste for Horses to GastroGard 370 mg/g Oral Paste.
•	06 February 2018	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from a new manufacturer.
•	30 August 2017	Change in the address of the marketing authorisation holder in BE, DK, FI, LU, NO, PT, ES & SE only.
•	09 August 2017	Deletion of manufacturing site for an active substance.
•	09 August 2017	Change in the specification limits of the finished product.
•	15 June 2017	Changes to a test procedure for the active substance.

•	06 April 2017	Change to part of the packaging material not in contact with the finished product formulation.
•	13 January 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance manufacturer.
•	20 October 2016	Renewal- UK as RMS
•	08 December 2015	Change in the QPPV and/or QPPV contact details and/or back-up procedure
•	21 August 2014	Submission of an updated Ph. Eur. Certificate of Suitability from an already approved manufacturer of the active substance.
•	12 June 2014	Change of MAH address in Portugal only.
•	16 January 2014	Change of MA holder address in Belgium only.
•	10 October 2013	Addition of a 14 syringe presentation.
•	17 September 2013	Approval of previously unseen mock ups.
•	11 July 2013	Change of a storage restriction for the finished product from 'store below 25C' to 'Do not store above 30˚C'. Change of shelf life to 18 months.
•	21 February 2013	Addition of a supplier of packaging components. Change of shape of container.
•	05 July 2011	Repeat use.
•	23 July 2010	Change in source of excipients.
•	30 December 2009	Submission of an updated Ph. Eur. Certificate of suitability for the finished product. Change of name of a manufacturing site of the finished product.
•	03 December 2009	Addition of pack size of 1 carton of 1 syringe.
•	21 August 2009	Renewal.
•	02 April 2009	Change of manufacturing site for all the manufacturing process except batch release.
•	09 March 2009	Change of batch size of the finished product.
•	13 May 2008	Changes to comply with Pharmacopoeia of a member state. Deletion of a manufacturing site for batch control and batch release.
•	22 October 2007	Change of name of manufacturing site of the finished product.
•	18 January 2007	Minor change in manufacturing process of the finished product.
•	04 October 2006	Change of legal category from POM to POM-V.
•	13 September 2006	Addition of an indication regarding prevention of gastric ulcers.
•	01 February 2006	Removal of a manufacturer of the active substance. Submission of an updated Ph. Eur. Certificate of Suitability for an active substance.
•	20 August 2004	Mutual recognition procedure, UK as RMS.