Veterinary Medicines Directorate

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

Post Authorisation Assessments

Tylan G250 Premix for Medicated Feedingstuff

Vm 00879/4173

•	30 August 2022	Change in the storage conditions of the finished product.
•	29 March 2022	Change in the name of the manufacturer of the finished product.
•	02 March 2022	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	23 December 2020	Change in immediate packaging of the liquid active substance. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	22 December 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release. Change in the name of the manufacturer of the finished product.
•	24 September 2020	Change of MAH from Eli Lilly and Company Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to Elanco Europe Ltd. Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	31 January 2019	Addition of a manufacturer responsible for batch release of the finished product. Addition of a site where batch control/testing takes place. Deletion of manufacturing site for an active substance.
•	21 May 2018	Changes to a test procedure for an excipient.
•	05 December 2017	Minor change in the manufacturing process of the active substance.
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•	05 December 2017	Deletion of a non-significant in-process test applied during the manufacture of the active substance. Minor change in the manufacturing process of the active substance.

•	30 March 2016	Deletion of a non-significant specification parameter.
•	01 May 2015	Minor change in the manufacturing process of the active substance.
•	12 November 2014	Change to the name of the active substance manufacturer.
•	11 September 2014	Amendments to the SPC and product literature in line with Commission Decision regarding an Article 35 referral procedure.
•	28 November 2013	Variation to update the current products with a number of minor changes in the manufacturing process of the active substance.
•	22 August 2013	Change in the shape or dimensions of the container (immediate packaging).
•	30 May 2013	Variation to introduce a test procedure used in the manufacturing process of the active substance.
•	28 May 2012	Variation to change the name of an active substance manufacturer.
•	21 December 2011	Variation to reduce a specification limit used in the manufacturing process of the active substance.
•	02 November 2010	Addition of an indication and withdrawal period information of the SPC and labelling.
•	21 January 2009	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from MFS to POM-V.
•	12 March 2008	Variation to remove the animal sourced TSE risk materials from the current starting materials used in the manufacture of the active substance.
•	04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
•	02 August 2007	Renewal.
•	02 May 2007	Change in the test procedure of the finished product.
•	25 September 2003	Renewal.
•	01 July 2003	Change in the pack details.
•	27 March 2001	Harmonisation of the SPC between the UK and IE.
•	17 July 1998	Addition of a packaging presentation.
•	12 March 1998	Amendment to the dosage particulars.
•	14 January 1998	Change of formulation of the finished product.