



Post Authorisation Assessments

Tylan G50 Premix for Medicated Feedingstuff Vm 52127/5086

25 November 2025	Change in the name of a site responsible for product manufacturing and testing.
07 August 2025	Change in immediate packaging of the active substance: - Liquid active substances -non-sterile.
12 June 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
29 April 2025	Change of Marketing Authorisation Holder from Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, D-27472 Cuxhaven, Groden, Germany. Change in distributor details from Elanco Europe Ltd. to Elanco UK AH Ltd.
13 March 2025	Replacement of the QC release testing site. Addition of alternate stability testing site. Replacement of one of the QP batch release sites.
22 July 2024	One-off alignment of the product information with version 9.0.
30 March 2022	Change in the name of the manufacturer 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.
05 December 2017	Minor change in the manufacturing process of the active substance.
05 December 2017	Minor change in the manufacturing process of the active substance.
05 December 2017	Minor change in the manufacturing process of the active

	substance.
05 December 2017	Minor change in the manufacturing process of the active substance.
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.
11 January 2017	Change to a test procedure for an excipient.
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.
24 June 2014	Deletion of a non-significant specification parameter.
28 November 2013	Variation to update the current products with a number of minor changes in the manufacturing process of the active substance.
28 November 2013	Variation to make changes to the specification parameters/limits of an excipient.
22 August 2013	Change in the shape or dimensions of the container (immediate packaging). Change in the test procedure for an excipient.
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.
02 May 2008	Renewal.
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.
14 February 2008	Change in the specification of an excipient.
04 January 2008	Variation to change the address of the Marketing Authorisation Holder.
19 December 2007	Change in the specification of an excipient.
02 May 2007	Change in the test procedure for the finished product.
21 May 2004	Renewal.
01 July 2003	Change in the packaging details.
15 November 2002	Change of manufacturing sites.
27 March 2001	Harmonisation of the SPC between the UK and IE.
31 December 1998	Variation concerning a change in the non-sterile containers.
31 December 1998	Change in the name of the Veterinary Medicinal Product.
31 December 1998	Change of the formulation of the finished product.