Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Tylan 200, 200 mg/ml Solution for Injection

Vm 00879/4204

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| • | 28 March 2022 | Change in the name of the manufacturer of the finished product. |
| • | 09 February 2022 | Change in distributor details from Eli Lilly and Company Ltd, Speke Operations, Fleming Road, Speke, Liverpool, L24 9LN to Elanco AH UK Limited, Form 2, Bartley Way, Bartley Wood Business Park, Hook, Hampshire, RG27 9XA United Kingdom |
| • | 06 January 2022 | Minor changes to an approved test procedure of the finished product. |
| • | 08 October 2021 | Addition of a site where batch control/testing takes place. |
| • | 18 February 2021 | 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. |
| • | 18 September 2020 | Change in the name of a manufacturer of the finished product, also responsible for batch release. |
| • | 20 May 2020 | Changes to the SPC/product labelling/package leaflet following an Article 35 referral. |
| • | 05 June 2019 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 12 February 2019 | Addition of a manufacturer responsible for batch release of the finished product.<br>Addition of a site where batch control takes place.<br>Deletion of manufacturing site for an active substance. |
| • | 16 August 2017 | Changes to the SPC/product labelling/package leaflet following a referral procedure. |
| • | 12 November 2014 | Change to the name of the active substance manufacturer. |
| • | 28 May 2012 | Variation to change the name of the active substance manufacturer. |
| • | 19 April 2011 | Addition of a site for labelling and packaging of the finished product. |
| • | 10 December 2008 | Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V. |
| • | 13 March 2008 | Addition of a safety warning to the administration section of the SPC. |
| • | 12 March 2008 | Minor change in the manufacturing process of the finished product. |
| • | 04 January 2008 | Variation to change the address of the Marketing Authorisation Holder. |
| • | 05 April 2006 | Addition of a new test parameter. |

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| • | 05 January 2006 | Renewal. |
| • | 31 October 2002 | Renewal. |
| • | 19 June 2002 | Addition of a pack size. |
| • | 19 June 2002 | Addition of a pack size. |
| • | 13 December 1999 | Reduction of the finished product shelf life. |
| • | 13 December 1999 | Minor changes in the manufacturing process of the veterinary medicinal product. |
| • | 28 August 1998 | Change of manufacturing of dosage form. |
| • | 09 December 1997 | Change of name of Marketing Authorisation Holder. |
| • | 10 October 1996 | Change of address of ATC/PL Holder. |