Veterinary Medicines Directorate

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Post Authorisation Assessments

Micotil 300 mg/ml Solution for Injection

Vm 00879/4203

•	01 April 2022	Change in the name of the manufacturer of the finished product.
•	10 February 2022	Change in distributor details from Eli Lilly & Company Ltd, Elanco Animal Health, Kingsclere Road, Basingstoke, Hampshire, RG21 6XA to Elanco UK AH Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, UK.
•	29 December 2021	Addition of a site where batch control/testing takes place.
•	10 November 2021	Decrease in batch size of active substance used in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance. Minor change in the manufacturing process of the active substance.
•	14 April 2021	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
•	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.
•	21 August 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	11 May 2020	Change(s) in the SPC, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent authority under Articles 45 or 46 of Regulation 1901/2006.
•	08 July 2019	To obtain joint labelling with Ireland.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	15 January 2019	Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site for an active substance.
•	05 December 2018	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	12 November 2014	Change to the name of the active substance manufacturer.
•	07 April 2014	Changes to the SPC and product following an EU Directive.
•	26 February 2014	Changes to the SPC and product literature following an EU Directive.

•	26 September 2013	Change in test procedure of the finished product.
•	28 May 2012	Change in the name of the manufacturer of the active substance.
•	19 April 2011	Addition of a manufacturer of labelling and packaging of the finished product.
•	13 April 2011	Change to a contact number found on the SPC and product literature.
•	12 January 2011	Change in test procedure for a starting material used in the manufacturing process of the active substance.
•	16 September 2009	Establishment of a withdrawal period in bovine milk.
•	11 December 2008	Change to SPC and product literature to bring them in line with new legislation.
•	4 January 2008	Change of address of the MAH.
•	15 November 2007	Minor change in the manufacturing process of the active substance.
•	15 November 2007	Change of manufacturer of the active substance.
•	4 October 2006	Change in test procedure for active substance or starting material, intermediate, or reagent used in the manufacturing process of the active substance.
•	25 July 2006	Change to user safety warnings.
•	21 June 2006	Change to use safety warnings.
•	19 April 2006	Renewal.
•	28 July 2005	Addition of an indication.
•	12 May 2004	Change to user safety warnings.
•	8 December 2003	Changes to the SPC and product literature regarding pack sizes.
•	28 February 2002	Renewal.
•	14 November 2000	Addition of an indication.
•	30 March 1999	Change to address of manufacturer of active substance.
•	2 June 1998	Renewal.
•	23 January 1998	Change to indications.
•	9 December 1997	Change of name and address of MAH.
•	19 October 1996	Addition of an indication.
•	20 September 1996	Change of name and address of MAH.