Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril 50 mg/ml Solution for Injection

Vm 00879/4119

•	15 September 2023	User safety warnings updated regarding potential allergic reactions to fluoroquinolones.
•	05 May 2023	Change in name of a manufacturer of the finished product.
•	13 October 2020	Change in the name and address of the manufacturer of the finished product.
•	17 September 2020	Change of MAH from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
•	05 May 2017	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD
•	09 August 2016	Change to more restrictive storage conditions of the active substance.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	30 March 2015	Change in specification of the finished product.
•	17 December 2014	Update of SPC and labelling due to a Commission decision.
•	20 November 2012	Change of in test procedure performed on the finished product
•	22 February 2011	Change of distributor
•	09 March 2009	Change of name of the manufacturer of the active substance
•	23 August 2007	Corrections to the SPC and Product Literature
•	20 July 2007	Changes to secondary packaging
•	12 July 2007	Change to in process control limits of the finished product
•	21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	14 September 2006	Renewal
•	31 January 2006	Change in test procedure on the finished product

•	05 August 2005	Change of secondary packaging
•	07 January 2005	Change of address of the manufacturer of the active substance
•	22 December 2004	Change of name of manufacturer of the finished product
•	02 December 2004	Harmonisation of the SPC
•	08 October 2004	Change in specification of the active substance
•	04 October 2004	Change in specification of the finished product
•	23 September 2004	Change of batch size of the active substance
•	05 December 2003	Change of address of the MAH
•	30 October 2002	Additional manufacturer responsible for assembly of the dosage form Additional manufacturer of the finished product
•	30 September 2002	Renewal
•	20 September 2002	Change of safety warnings regarding visual abnormalities in cats
•	29 March 2000	Change in specification of the active substance Change in manufacturing process for active substance
•	04 June 1998	Update to licence particulars
•	30 December 1997	Renewal
•	11 October 1995	Change to specification of the finished product