Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril 100 mg/ml Solution for Injection

Vm 00879/4116

•	15 September 2023	User safety warnings updated regarding potential allergic reactions to fluoroquinolones.
•	08 March 2022	Change in control of excipients in the finished product.
•	10 February 2022	Change in the name of the 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 to in-test procedure performed on the finished product
•	23 February 2011	Change of distributor
•	09 March 2009	Change of manufacturer of the active substance
•	18 March 2008	Decrease in withdrawal period for meat from cattle when product used subcutaneously from 14 days to 7 days
•	10 March 2008	Renewal
•	23 August 2007	Corrections to SPC and Product Literature
•	20 July 2007	Change to immediate packaging
•	12 July 2007	Change of in process limits of the finished product
•	13 March 2007	Line extension

•	31 January 2006	Change in test procedure for the finished product
•	05 August 2005	Change to secondary packaging
•	07 January 2005	Change to address of the manufacturer of the active substance
•	22 December 2004	Change of name and address of the manufacturer of the finished product
•	26 November 2004	Harmonisation of SPC
•	08 October 2004	Change to the specification of the active substance
•	23 September 2004	Change in batch size of the active substance
•	16 April 2004	Change to specification of the finished product
•	15 January 2004	Renewal
•	05 December 2003	Change of address of the MAH
•	31 October 2002	Addition of a manufacturer responsible for assembly Addition of a manufacturer of the finished product
•	21 June 2000	Renewal
•	28 March 2000	Change in manufacturing process of the active substance Change to specification of the finished product
•	02 July 1999	Addition of a milk withdrawal period
•	08 June 1998	Update of licence particulars