



Post Authorisation Assessments

Baytril 25 mg/ml Solution for Injection

Vm 00879/4118

•	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 for the finished product
•	22 February 2011	Change of distributor
•	09 March 2009	Change of manufacturer of the active substance
•	20 July 2007	Change to secondary packaging composition
•	12 July 2007	Change to limits for in process control of the finished product
•	21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	15 September 2006	Renewal
•	31 January 2006	Change in test procedure on the finished product
•	05 August 2005	Change to secondary packaging composition
•	07 January 2005	Change of address for the manufacturer of the active substance

•	22 December 2004	Change of name of manufacturer of the finished product
•	24 November 2004	Harmonisation of the SPC
•	08 October 2004	Change to specification of the active substance
•	29 September 2004	Change to specification of the finished product
•	23 September 2004	Change in batch size
•	05 December 2003	Change of address of MAH
•	31 October 2002	Addition of an assembler of the dosage form Addition of a manufacturer of the dosage form
•	27 September 2002	Renewal
•	20 September 2002	Change to safety warnings regarding visual impairment of cats
•	28 March 2000	Change to specification of the active substance Change to manufacturing process of active substance
•	08 June 1998	Update of licence particulars
•	03 February 1998	Use in additional species (non-food)
•	05 March 1997	Renewal
•	11 October 1995	Change to specification of the finished product