Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Baytril 25 mg/ml Solution for Injection

Vm 52127/3044

15 January 2026	Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product. Addition of quality control testing site for the finished product.
04 September 2025	Change of distributor details from Elanco Europe Ltd to Elanco UK AH Ltd. Change of legal entity of the Marketing Authorisation Holder from Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, 27472 Cuxhaven, Germany.
14 July 2025	Change in the name of a manufacturer of the finished product.
30 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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