Veterinary Medicines Directorate

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

Post Authorisation Assessments

Baytril Flavour Tablets 150 mg

Vm 52127/3063

04 November 2026	Deletion of a manufacturer of the finished product.
21 May 2026	Addition of contact details for Northern Ireland to report suspected adverse reactions for the Marketing Authorisation Holder.
22 October 2025	Change in legal entity of MA 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. Change in name of distributor from Elanco Europe Ltd to Elanco UK AH Ltd.
05 September 2025	Alignment of the product information with version 9.0* of the QRD templates.
04 September 2025	Submission of a Ph. Eur. CEP for an active substance.
16 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance.
15 September 2023	User safety warnings updated regarding potential allergic reactions to fluoroquinolones.
28 March 2023	Addition of a primary packaging site. Addition of a secondary packaging site.
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.
08 October 2019	Change in the specification limits.
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
19 September 2016	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product
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.
03 April 2014	Changes to labelling not connected to the SPC
17 August 2012	Changes in the qualitative and quantitative composition of the immediate packaging
22 February 2011	Change of distributor
04 September 2009	Increase of shelf life of the finished product from 3 years to 5 years
24 June 2009	Change of specification of the active substance
09 March 2009	Change of name of manufacturer of the active substance
21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
14 September 2006	Renewal
18 January 2005	Harmonisation of SPC
07 January 2005	Change of address of the manufacturer of the active substance
08 October 2004	Change in specifications of the active substance
23 September 2004	Change of batch size of the active substance
30 January 2004	Change of address of MAH
22 December 2003	Change in flavouring system
10 October 2003	Change in name of the product from ‘Baytril Tablets 150mg’ to ‘Baytril Flavour Tablets 150mg’
06 August 2002	Renewal
11 October 2001	Change of ingredient formulation Change of ingredient specification Change of in-process controls applied during the manufacture of the finished product
07 March 2001	Change of type of non-sterile containers
28 March 2000	Change in specification of the active substance Change in manufacturing process for active substance
04 June 1998	Update of licence particulars
15 July 1997	renewal
31 July 1996	Change to specification of the finished product