Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril 25 mg/ml Oral Solution

Vm 52127/5160

31 July 2026	Editorial change to part 2 of the dossier.
14 March 2026	Submission of mock ups.
17 November 2025	Change in name of distributor from Elanco Europe Ltd to Elanco UK AH Ltd. 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.
12 November 2025	Increase in the batch size of the finished product.
10 November 2025	Increase in the batch size of the finished product.
23 October 2025	Alignment of the product information with version 3 of the National QRD templates.
30 July 2025	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
30 April 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
27 October 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
15 September 2023	User safety warnings updated regarding potential allergic reactions to fluoroquinolones.
06 May 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance.
08 October 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.
12 June 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
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 June 2018	Deletion of a supplier of packaging components or devices.
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.
12 April 2011	Change in shape/dimensions of the immediate packaging
16 February 2011	Change of distributor
09 March 2009	Change in name of manufacturer of the active substance
08 February 2008	Renewal
12 September 2007	Corrections to the SPC and Product Literature
21 September 2006	Changes to the SPC and Product Literature to bring in line with new legislation
07 January 2005	Change of manufacturer of the active substance
24 November 2004	Harmonisation of the SPC
08 October 2004	Change to specification of the active substance
23 September 2004	Change to the batch size of the active substance
11 March 2004	Renewal
30 January 2004	Change to MAH address
13 June 2001	Change to specification of the finished product
21 June 2000	Renewal
29 March 2000	Change in specification of the active substance Change of manufacturing process of the active substance
04 June 1998	Update of licence particulars
29 January 1998	Use in additional non-food species (Exotic animals and avian species)
05 March 1997	Renewal