



Post Authorisation Assessments

Baytril 100 mg/ml Solution for use in Drinking Water for Chickens, Turkeys and Rabbits Vm 52127/5104

13 February 2026	Update to MIC data in line with the "Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances" (EMA/CVMP/383441/2005). One-off alignment of the product information with version 3 of the National QRD templates.
08 August 2025	Submission of a new Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
26 June 2025	Change in distributor details from Elanco Europe Ltd. to Elanco UK AH Ltd. Change of 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.
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.
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.
01 October 2019	Change in container closure system of the finished product.
12 June 2019	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
02 October 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
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.
22 June 2018	Changes to the SPC/product labelling/package leaflet following an Article 35 referral.
12 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
13 July 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.
06 March 2015	Change in SPC, labelling and package leaflet following a Referral procedure.
29 April 2014	Update of SPC and product literature following an EU Commission decision
14 October 2013	Submission of a new certificate of suitability
23 May 2013	National harmonised variation
27 December 2012	Change to SPC and Product Literature
20 June 2012	referral
23 February 2011	Change of distributor
09 March 2009	Change of name of the manufacture of the active substance
02 April 2008	Change to manufacturing process of the finished product Change to in-process tests/limits applied during the manufacture of the product
07 March 2008	Renewal
23 August 2007	Corrections to the SPC and Product Literature
13 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation
07 January 2005	Change of address of the manufacturer of the active substance
08 October 2004	Change in specification of the active substance
23 September 2004	Change in batch size of the active substance
22 September 2004	Renewal
05 December 2003	Change of MAH address
13 June 2003	Change in specification of the finished product
22 June 2000	Renewal
31 March 2000	Change in specification of the finished product Change to manufacturing process
04 June 1998	Update of licence particulars
16 April 1996	Additional presentation