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 52127/5138

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| 04 November 2026 | Deletion of a manufacturer of the finished product. |
| 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.<br>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.<br>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<br>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.<br>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 |

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| | 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<br>Change of ingredient specification<br>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<br>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 |