Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril Flavour Tablets 50 mg

Vm 00879/4122

•	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 the 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 in shelf life of finished product from 3 years to 5 years
•	24 June 2009	Change of specification of the active substance
•	09 March 2009	Change in 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 ingredient
•	08 October 2004	Change in specification of the active substance
•	23 September 2004	Change to batch size of the active substance
•	03 February 2004	Change of MAH address
•	22 December 2003	Change to flavouring system
•	09 October 2003	Change of product name from 'Baytril Tablets 50mg' to 'Baytril Flavour Tablets 50mg'
•	06 August 2002	Renewal
•	11 October 2001	Changes to in process controls applied during the manufacture of the dosage form
•	07 March 2001	Renewal
•	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