Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril 10% Oral Solution

Vm 00879/4115

•	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