



Post Authorisation Assessments

Baytril Piglet Doser 0.5% Oral Solution

Vm 00879/4124

•	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.
•	21 August 2019	Reduction of the shelf life of the finished product as packaged for sale from 36 months to 30 months.
•	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 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
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	23 February 2011	Change of distributor
•	09 March 2009	Change of name of manufacturer of the active substance
•	08 February 2008	Renewal
•	12 September 2007	Corrections to the SPC
•	21 September 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 to specification of active substance
•	23 September 2004	Change of batch size of active substance
•	12 March 2004	Renewal
•	18 September 2003	Change of MAH address
•	13 June 2003	Change in specification of the finished product
•	17 June 2002	Harmonisation of the SPC

•	21 June 2000	Renewal
•	28 March 2000	Change in specification of the active substance Change of control tests on the active substance Change of manufacturing process of the active substance
•	08 June 1998	Update of Licence particulars