Veterinary Medicines Directorate

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Post Authorisation Assessments

Baytril Max 100 mg/ml Solution for Injection for Cattle

•	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.
•	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.
•	20 November 2012	Variation to change an in test procedure for the finished product.
•	23 November 2011	Change of the name of the veterinary medicinal product.
•	22 February 2011	Variation to change the distributor.
•	14 May 2009	New National Extension.
•	09 March 2009	Variation to change the name of the active substance manufacturer.
•	20 November 2008	Change in the specification of the finished product.
•	10 November 2008	Renewal.
•	10 November 2007	Variation to change the dimensions of the primary container.
•	23 August 2007	Variation to change Section 4.5 of the SPC and Product Literature.
•	21 September 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	24 August 2005	Variation to change the test methods to comply with the European Pharmacopoeia.
•	11 August 2005	Harmonisation.
•	07 January 2005	Variation to change the name of an active substance manufacturer.
•	31 December 2004	Change of name of the manufacturer of the finished product.
•	17 November 2004	Renewal.
•	08 October 2004	Variation to change the active substance specifications.
•	23 September 2004	Variation to change the batch size.
•	30 January 2004	Variation to change the address of the Marketing Authorisation Holder.
•	06 January 2000	Change in the test methods.
•	06 January 2000	Change of the release specification.
•	06 January 2000	Change in the synthesis route of the finished product.
•	29 November 1999	Change of batch size.

•	16 November 1999	Deletion of a contraindication from the SPC and Package Leaflet.