Veterinary Medicines Directorate

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Post Authorisation Assessments

Bisolvon 10 mg/g Oral Powder

Vm 08327/5072

17 July 2024	Change in dimensions of the container for the finished product. Change in dimensions of the container for the finished product.
12 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
12 July 2022	Minor change to an approved test procedure for a finished product identification.
09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
23 July 2018	Submission of an updated Ph. Eur. Certificate of Suitability.
05 April 2018	Updates to the SPC and package leaflet.
21 November 2016	Deletion of approved batch sizes of the finished product.
03 May 2016	Change in the specification limits of the finished product
09 December 2015	Change in part of the primary packaging material not in contact with the finished product.
09 September 2013	Deletion of a site of secondary assembly Deletion of a manufacturer of the finished product Deletion of a manufacturer of the active substance
01 May 2013	Changes to test procedures performed on the finished product
01 March 2012	Deletion of a site of assembly
09 February 2012	Deletion of a manufacturing site of the active substance, finished product and assembly
01 September 2011	Change of batch size of the finished product Change to the manufacturing process
11 May 2010	Change in specification of the finished product
03 April 2009	Renewal
31 March 2009	Submission of a new Ph. Eur. Certificate of Suitability for an active substance
03 July 2008	Change of legal category from POM to POM-V Changes to bring the SPC and Product Literature in line with new legislation Removal of horses not for human consumption from the target species
27 October 2006	Change in batch size of the finished product
21 June 2006	Addition of a new test performed on the finished product Change to specification of the finished product

29 September 2004	Changes to the SPC and Product Literature to bring in line with new legislation
08 April 2004	Change of withdrawal period for Cattle meat to 2 days
08 April 2004	Renewal
08 April 2004	Review