



Post Authorisation Assessments

Bisolvon 10 mg/g Oral Powder Vm 08327/4290

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| • | 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 |

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| • | 08 April 2004 | Renewal |
| • | 08 April 2004 | Review |