



Post Authorisation Assessments

Buscopan 20mg/ml Solution for Injection for Horses and Calves Vm 08327/5045

•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 April 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 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.
•	20 February 2012	Deletion of a specification parameter for the active substance.
•	17 February 2011	Addition of site of batch release.
•	03 June 2010	Replacement of a manufacturing site for all parts of manufacturing operations of the finished product except batch release and control testing.
•	16 July 2009	Submission of two updated Ph. Eur. Certificates of Suitability from already approved active substance manufacturers.
•	24 July 2008	Approval of unseen mock ups.
•	18 April 2008	Change in batch size of the active substance.
•	31 March 2008	Change of specification of the finished product.
•	01 August 2007	Renewal.
•	18 December 2006	Change of name of the site of batch release.