Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Combiclav Suspension for Injection

Vm 02000/4238

•	03 July 2023	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
•	20 December 2022	Editorial changes to part 2b of the dossier.
•	22 November 2022	Submission of a new Ph.Eur certificate of suitability for an active substance.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	11 May 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	14 April 2021	Minor change in the manufacturing process of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product.
•	08 July 2020	Minor changes to an approved test procedure of the finished product.
•	08 July 2020	Change in test procedure to reflect compliance with the Ph. Eur. and remove reference to outdated internal test methods and test method numbers.
•	14 August 2019	Replacement of a supplier of packaging components or devices.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	17 January 2019	Minor changes to an approved test procedure of the finished product.
•	17 January 2019	Introduction of a new site of manufacture.
•	27 July 2018	Changes to the labelling and package leaflet. Update distributor details on the QRD text.
•	19 July 2018	Replacement of a secondary packaging site of the

		finished product.
•	02 July 2018	Change of specification of a former non Pharmacopoeial excipient to comply with the Ph. Eur. Specifications. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 February 2016	Deletion of a manufacturing site for the active. Submission of an updated certificate of suitability. Submission of a new certificate of suitability.
•	21 November 2013	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved active substance manufacturer.
•	08 January 2009	Changes to the SPC and Product Literature to bring in line with new legislation
•	08 August 2008	Renewal
•	15 July 2008	Submission of updated Ph. Eur. Certificates of Suitability for active substances from an already approved manufacturer
•	19 June 2008	Deletion of a manufacturer of an active substance
•	16 January 2008	Addition of a manufacturer of an active substance Addition of a manufacturer of an active substance
•	28 March 2007	Change of legal category from POM to POM-V
•	24 August 2005	Addition of an indication for use with Combiclav LC