Veterinary Medicines Directorate

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Post Authorisation Assessments

Aloquantel Ivermectin and Praziquantel Oral Gel for Horses

•	10 September 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 April 2021	Deletion of a non-significant specification parameter of the finished product.
•	11 January 2021	Replacement of manufacturer responsible for batch control. Replacement of a manufacturer responsible for batch release of the finished product. Deletion of manufacturing site for a finished product.
•	11 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	16 April 2020	Change in the fill weight of the finished product. Change in the invented name of the veterinary medicinal product from Virbac Ivermectin And Praziquantel Oral Gel for Horses to Aloquantel, Ivermectin And Praziquantel Oral Gel For Horses. Change in distributor details from Virbac Ltd, Suffolk IP30 9UP, UK to Farm & Stable Supplies LLP, Omega House, Lakesmere Road, Hazleton Interchange, Horndean, PO8 9JU.
•	02 September 2019	Deletion of manufacturing site. Submission of a new Ph. Eur. certificate of suitability for an active from a new manufacturer. Introduction of a re-test period of the active substance.
•	09 May 2019	Change in the manufacturing process of the finished product.
•	03 May 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 January 2018	Change in test procedure for the active substance.
•	03 January 2018	Update of the test procedure to comply with the updated general Ph. Eur monograph.
•	04 December 2017	A number of minor changes to the manufacturing process.
•	22 November 2016	Up to 10-fold increase in batch size compared to the currently approved batch size of the finished product.
•	27 July 2016	Change in test procedure for the finished product. Change in test procedure for the finished product. Change in test procedure for the finished product.

		Deletion of a non-significant specification parameter. Submission of a new or updated Ph. Eur. certificate of suitability. Change outside the approved specifications limits range.
•	30 March 2015	Submission of new certificates of suitability.
•	29 November 2012	Variation to change the Marketing Authorisation Holder.
•	06 November 2012	Grouped variation to submit an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer. Extension of the active substance retest period.
•	07 June 2012	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	12 January 2011	Variation to change the address of the Marketing Authorisations Holder.
•	03 February 2010	Renewal.