Veterinary Medicines Directorate

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

Post Authorisation Assessments

Eqvalan Oral Paste for Horses (Ivermectin 18.7 mg/g)

Vm 08327/4177

•	07 March 2024	Editorial changes to the package leaflet.
•	03 August 2023	Change in the name of a manufacturer of the finished product.
•	11 April 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	10 August 2022	Change in address for manufacturer of the finished product.
•	14 April 2022	Addition of a new container for the finished product. Change in the fill weight of the finished product. Change in the fill weight of the finished product. Change in shape or dimensions of the container or closure (immediate packaging).
•	09 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	28 May 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	03 May 2019	Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product.
•	07 February 2019	Change in the name of the manufacturer of the finished product.
•	02 January 2019	Change in the manufacturing process of the active substance.
•	01 November 2018	Change in the name and address of the marketing authorisation holder from Merial Animal Health Ltd, Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex, CM19 5TG to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	28 February 2017	Change to part of the (primary) packaging material not in contact with the finished product formulation.
•	29 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	20 October 2015	Submission of an updated certificate of suitability for a manufacturer of an active substance.
•	03 September 2013	Addition of a manufacturer responsible for batch release.
•	07 June 2013	Grouped variation concerning: a change in manufacturing process for the finished product, a change in the batch size of the finished product, and a change in the specification parameters of the finished product.

•	26 June 2012	Deletion of an active substance manufacturer.
•	18 August 2010	Correction/Simple text layout changes to SPC.
•	30 September 2008	Renewal.
•	03 April 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.
•	07 December 2007	Variation to make a minor change to the finished product manufacture.
•	07 December 2007	Replacement of a site for the manufacturing processes of the finished product. Addition of a manufacturer responsible for batch testing and release.
•	29 November 2007	Addition of an active substance manufacturer.
•	29 November 2007	Addition of an active substance manufacturer.
•	11 November 2007	Change in the finished product batch site.
•	20 July 2005	Renewal.
•	04 June 2004	Variation to update the monographs for the active substance and excipients.
•	04 June 2004	Variation to update the manufacturing methods.
•	04 June 2004	Variation to update the finished product specification and associated test method.
•	11 February 2004	Variation to register firm specifications for substance related to the active substance in the finished product.
•	05 March 2001	Renewal.
•	25 October 2000	Change to the finished product specifications.
•	27 July 2000	Change to the Indiciations for use.
•	27 July 1999	Variation to update the finished product specifications.
•	19 May 1999	Variation to update the target species.
•	18 June 1998	Variation to change the Marketing Authorisation Holder.