Veterinary Medicines Directorate

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

Post Authorisation Assessments

Vetivex 1 (9 mg/ml) Solution for Infusion for Cattle, Horses, Dogs and Cats

Vm 10434/4079

•	23 February 2024	Change in pack size within the range of the currently approved pack size. Change in pack size within the range of the currently approved pack size. Change in pack size within the range of the currently approved pack size. Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Addition of a manufacturer responsible for batch release including batch control or testing of a non- sterile finished product. Replacement or addition of a secondary packaging site of a finished product.
•	23 February 2024	Change in dimensions of the immediate packaging. Change in the testing frequency of specification parameter. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product. Submission of a new Ph. Eur. certificate of suitability.
•	07 July 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. (NI)
•	16 January 2023	Change to update the specification of an active substance to comply with the current Ph. Eur.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	20 November 2018	Renewal – UK as RMS.
•	01 August 2018	Change in RMS from UK to IE.
•	24 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 November 2017	Deletion of manufacturing site. Deletion of manufacturer responsible for batch release.
•	05 January 2016	Addition of a manufacturer responsible for batch release Addition of a secondary packaging site Submission of a new or updated Ph. Eur. certificate of suitability

		Changes in test procedure for the finished product Minor changes in the manufacturing process Addition of a manufacturing site of the finished product
•	02 December 2015	Variation to change the address of the marketing authorisation holder from Dechra Limited, Jamage Industrial Estate to Dechra Limited, Snaygill Industrial Estate.
•	19 March 2015	Change of shelf life for the finished product as packaged for sale in the 500 ml, 1000 ml and 2000 ml presentations from 18 months to 2 years.
•	30 October 2014	Variation to introduce multi-pack sizes of 50 x 100 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml.
•	05 June 2014	To change the manufacturing site of the active substance.