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

•	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.