

## Post Authorisation Assessments

### Hyperimmune-RE Equine Plasma

Vm 18513/4001

08 April 2025	Submission of updated mock ups.
01 April 2025	Change in the address of the marketing authorisation holder from: Carleton Hill, Penrith, Cumbria, CA11 8TZ, United Kingdom to Lynefoot Farm, Westlinton, Cumbria, England, CA6 6AJ, United Kingdom.
19 January 2025	To increase the shelf life from 24 to 36 months. To change the storage condition to <-15°C.
18 January 2025	To move the site of production to Lynefoot Farm, Westlinton. IgG and RE Antibody testing are moved from the VIL Carleton Site Laboratory to the Lynefoot Farm Laboratory site. Sterility and pH Quality Control Testing are moved from Lucideon Limited to the Lynefoot Farm Laboratory Site.
21 November 2023	Total protein to be tested at Biobest Laboratories Ltd. IgG to be tested at Veterinary Immunogenics Laboratory using Radial Immunodiffusion test kits.
07 September 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance.
09 May 2023	Change in immediate packaging of the active substance.
28 July 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
17 December 2021	Change in the manufacturer of an intermediate used in the manufacturing process of the active.
17 March 2021	Addition of a site where batch control/testing takes place.
29 September 2020	Change in the specification limits of the finished product.
11 June 2020	Replacement of a site where batch control/testing takes place. Replacement of a site where batch control/testing takes place.
09 April 2019	Change in RMS from UK to IE
16 November 2012	Change of test procedure used during the manufacturing process.
26 June 2012	Variation to increase the release titre for the potency test.
09 May 2012	Renewal procedure, UK as RMS.
04 August 2008	New MA (MRP)
21 June 2007	Variation to add a new QC contract test laboratory