Veterinary Medicines Directorate

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

Post Authorisation Assessments

Genta-Equine 100 mg/ml Solution for Injection for Horses

Vm 33848/4000

17 February 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI) Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
06 January 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (GB)
06 January 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
09 December 2025	Change in the address of the marketing authorisation holder from Franklin Pharmaceuticals Ltd, Eamon Duggan Industrial Estate, Athboy Road, Trim, Co. Meath, C15 XA09, Ireland to Franklin Pharmaceuticals Ltd, 13 Fulmar, Barnageeragh Cove, Skerries, Dublin, K34 W110, Ireland. (GB + NI).
09 December 2025	Addition of Local Representative Dechra Veterinary Products Limited Sansaw Business Park Hadnall Shrewsbury Shropshire SY4 4AS United Kingdom Tel: +44 (0) 1939 211200.
11 November 2021	Minor change in the manufacturing process of the finished product. Change in the batch size (from 500 litres to 1400 litres) of the finished product.
13 September 2021	Change in immediate packaging of the active substance. Replacement of a site where batch control / testing takes place. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
09 September 2019	Change of RMS from UK to BE.
06 February 2019	Renewal - UK as RMS.
21 September 2017	Replacement of a manufacturer responsible for batch release including batch control/testing. Replacement of a secondary packaging site of the finished product. Replacement of a manufacturing site of the finished product.
15 August 2017	Deletion of manufacturing site responsible for batch release and packaging
04 May 2017	Addition of a manufacturer of the active substance.
06 October 2016	Mock-ups approved.
24 May 2016	Addition of a manufacturer responsible for batch release.

12 January 2016	Addition of a manufacturing site for secondary packaging.
21 May 2015	Changes to SPC and product labelling following a referral procedure.
16 December 2010	Addition of a manufacturer and an analytical procedure.
08 December 2010	To make changes to the product literature.
24 November 2010	To change the distributor.
26 October 2010	Change to batch release arrangements and quality control testing of the finished product.