Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 33848/4000

•	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.