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

Post Authorisation Assessments

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care Solution for Infusion for Cattle, Horse, Sheep, Goat, Pig, Dog and Cat

Vm 03551/3000

•	05 June 2023 14 December 2022	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
•		Update to a Ph.Eur certificate of suitability for the active substance. Update to a Ph.Eur certificate of suitability for the active substance.
•	02 December 2021	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product.
•	15 February 2021	Deletion of manufacturing site for an active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 July 2020	Changes to the labelling and/or package leaflet.
•	24 December 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	07 February 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 June 2018	Renewal - UK as CMS.
•	23 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 February 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	06 October 2015	Submission of an updated certificate of suitability from an already approved manufacturer.

	•	01 May 2015	Submission of new or updated Ph. Eur. Certificates of suitability. Changes to the DDPS.
ľ	•	24 September 2014	Repeat Use Comms.