

Post Authorisation Assessments

B. Braun Vet Care Hypertonic NaCl Solution (7.5 g/100 ml) Solution for Infusion for Horses, Cattle, Sheep, Goats, Pigs, Dogs and Cats Vm 03551/4003

06 March 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
22 June 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
23 April 2024	Minor changes to an approved test procedure for the finished product. (NI)
18 August 2023	Minor change to an approved test procedure for the finished product. (GB)
06 April 2023	Variation related to the introduction of parametric release in the manufacture of the finished product.
02 November 2022	Updated Ph.Eur. certificate of suitability for an active substance. Updated Ph.Eur. certificate of suitability for an active substance.
17 March 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.
24 December 2019	Change in the invented name of the veterinary medicinal product in Italy only, from B. Braun VetCare ipertonica NaCl-Soluzione (7,5 g/100 ml) soluzione per infusione per cavalli, bovini, pecore, capre, suini, cani e gatti to Sodio Cloruro 7,5 g/100 ml B. Braun VetCare soluzione ipertonica per infusione per cavalli, bovini, pecore, capre, suini, cani e gatti.
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.
07 November 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
15 February 2017	Submission of an updated certificate of suitability.
27 September 2016	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system (e.g. change of the major storage/archiving location, administrative changes).
24 July 2015	Grouped variation to update the Certificates of Suitability for the active substance, and to add a new certificate of suitability from

	an already approved manufacturer.
02 July 2015	Update to the DDPS.
19 August 2014	Renewal.
03 July 2013	Submission of a new Ph. Eur. Certificate of Suitability for an active substance from 3 already approved manufacturers.
03 April 2013	Introduction of a new pharmacovigilance system description of B. Braun Melsungen AG.
28 August 2012	To change the Marketing Authorisation Holder from B. Braun Vet Care GmbH to B. Braun Melsungen AG.