Veterinary Medicines Directorate

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Post Authorisation Assessments

Hypertonic 72 mg/ml Solution for Infusion for Cattle, Cattle (Calves), Horses, Dogs and Cats

Vm 50406/3033

29 September 2026	Submission of a new CEP for the manufacture of an active substance.
17 July 2026	Editorial changes to part 2 of the dossier.
19 June 2026	Change to comply with an update of the relevant monograph of the Ph. Eur.
11 November 2025	Alignment of the product information with version 9.0* of the QRD templates.
14 August 2025	Change in pack size within the range of the currently approved pack size. Change in pack size within the range of the currently approved pack size.
14 August 2025	Change in the manufacturing process of the finished product. Addition of a manufacturing site for the finished product. Submission of a new Ph. Eur. certificate of suitability.
25 April 2025	Change of Marketing Authorisation Holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
30 December 2022	Replacement certificate of suitability from a new manufacturer.
23 March 2022	Renewal
18 March 2019	Change in RMS from UK to BE.
12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
24 July 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.