Veterinary Medicines Directorate

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Post Authorisation Assessments

Hypertonic 7.2% w/v Solution for Infusion,
Vm 10434/4056

•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	14 July 2016	Minor changes in the manufacturing process as a consequence of the addition of SC Infomed Fluids SRL as a site of manufacture which was approved on 03/06/2016.
•	14 July 2016	Update the specification for Particle Contamination in the Finished Product Specification for the above product. - Alignment to Ph. Eur.
•	03 June 2016	Addition of a manufacturer responsible for batch release including batch testing. Addition of a secondary packaging site of the finished product. Addition of a manufacturing site of the finished product.
•	12 February 2016	Change in the address of the Marketing Authorisation Holder from Dechra House, Jamage Industrial Estate, Talke Pits,Stoke-on-Trent, ST7 1XW, UK. to Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom.
•	14 August 2015	Deletion of non-significant specification parameters and/or limits of the finished product.
•	17 March 2015	Change in the invented name of the veterinary medicinal product from 'Vetivex 20 (Sodium Chloride 7.2% w/v Intravenous Infusion)' to 'Hypertonic 7.2% w/v Solution for Infusion'.
•	08 August 2012	Variation to change the composition of the primary packaging.
•	24 April 2012	Variation to change the name of a manufacturer.
•	19 January 2011	Variation to change the distributor.
•	22 December 2010	Variation to change the name of a manufacturer.
•	28 July 2010	Variation to make corrections to the SPC/Product Literature.
•	30 September 2008	Variation to change the Marketing Authorisation Holder.
•	09 May 2008	Renewal.
•	20 December 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category.
•	07 September 2005	Variation to change the active substance manufacturer.
•	01 August 2005	Variation to change the name and address of the

		Marketing Authorisation Holder.
•	22 December 2004	Change of the name of a manufacturer/assembler of the finished product.
•	25 November 2004	Renewal.
•	11 November 2004	Addition of a distributor.
•	03 December 2003	Addition of an active substance manufacturer.