Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetivex 18 (Sodium Chloride 0.18% w/v and Glucose 4% w/v Intravenous Infusion B.P. (Vet))

Vm 10434/4058

•	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.
•	13 July 2016	Specification update. Specification update.
•	03 June 2016	Addition of a site of batch release and batch testing. Addition of a site of secondary packaging for the finished product. Addition of a site of manufacturing and primary packaging for 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.
•	08 August 2012	Variation to change the composition of the immediate packaging of the finished product.
•	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 the manufacturer.
•	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	Change of active substance manufacturer.
•	05 August 2005	Change of Marketing Authorisation Holder.
•	22 December 2004	Variation to change the name of an assembler.
•	30 November 2004	Renewal.
•	22 October 2004	Addition of a distributor.
•	28 November 2003	Addition of an active substance manufacturer.