Veterinary Medicines Directorate

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Post Authorisation Assessments

Voren Suspension for Injection, 1 mg/ml

•	09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	31 March 2015	Minor change to an approved test procedure for the finished product.
•	15 January 2014	Variation to increase the retest period of the active substance.
•	24 July 2013	Grouped variation concerning: a change in the manufacturing process of the active substance, the deletion of an active substance manufacturer, a change in the specification parameters/limits of the active substance.
•	09 October 2012	Deletion of an active substance manufacturer.
•	27 April 2012	Submission of an updated Certificate of Suitability for an already approved active substance manufacturer.
•	16 December 2009	Deletion of an active substance manufacturer (responsible for manufacture of dosage form).
•	02 December 2009	Addition of a safety warning.
•	02 April 2009	Variation to increase a withdrawal period (cattle milk).
•	04 February 2009	Submission of a new or updated European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	08 January 2009	Renewal.
•	20 December 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	22 August 2006	Addition of an active substance manufacturer.
•	21 July 2006	Submission of a new or updated European Pharmacopoeia Certificate of Suitability for an active substance manufacturer.
•	28 June 2006	Variation to comply with the European Pharmacopoeia.
•	03 March 2005	Renewal.
•	29 September 2004	Horse Passport Scheme.
•	26 March 2004	Variation to reduce the finished product shelf life.
•	22 January 2004	Change to the pig withdrawal period.
•	22 January 2004	Change to the cattle withdrawal period.
•	29 May 2003	Change to the active substance testing specification.
•	29 May 2003	Change to the finished product testing specification.
•	30 April 2003	Variation to change the name of a manufacturer/assembler.

•	05 April 2002	Variation concerning the increase of a withdrawal period.
•	28 March 2002	Renewal.
•	18 October 2001	Change in the batch size of the finished product.
•	18 October 2001	Change to the in-process controls applied during the manufacturing process of the active substance.
•	18 October 2001	Change to the manufacturing specifications.
•	26 June 2001	Change to a withdrawal period.
•	06 April 2000	Change to the name of a manufacturer.
•	26 October 1998	Change to the finished product specification.
•	23 October 1998	Change to the finished product specification.
•	29 May 1998	Variation concerning the assembler of dosage form.
•	29 May 1998	Change of secondary assembler.
•	15 October 1997	Addition of an active substance manufacturer.
•	22 January 1997	Change to the manufacturing specification.
•	20 November 1996	Change to the ingredient specification.
•	14 November 1996	Change to the testing specifications for the active substance.
•	19 September 1996	Change to the route of synthesis of the active substance.
•	19 September 1996	Change to the formulation of the finished product.
•	06 September 1996	Addition of a manufacturer/assembler of dosage form.
•	06 September 1996	Change of formulation of the finished product.
•	19 February 1996	Addition of a formulation (ATC only).