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Post Authorisation Assessments

Nobilis Salenvac Vm 01708/4389

	04.0.4.1.0000	
•	01 October 2020	Change in the name of a manufacturer of the finished product, also responsible for batch release.
•	22 September 2020	Minor changes to an approved test procedure of the finished product.
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		Addition of a site where batch control/testing takes place.
•	11 September 2020	Change in the name of a manufacturer used in the manufacture of the active substance.
•	14 August 2020	Change in the name of the marketing authorisation holder from Intervet UK Limited to MSD Animal Health UK Limited.
•	26 April 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	16 April 2019	Deletion of a non-significant specification parameter of the finished product.
		Change in the manufacturing process of the finished
		product, including an intermediate used in the
		manufacture of the finished product.
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•	21 August 2018	Change in RMS from UK to IT.
•	29 September 2015	Change in the manufacturing process of the finished product.
•	30 March 2012	Change in the name of the manufacturer of the finished product.
•	22 October 2010	Renewal.
•	28 October 2009	Addition of a filling site of the finished product.
•	25 September 2008	Variation to update the detailed description of the
•	23 July 2007	Production process. Variation concerning the routine application of the batch
	02 September 2005	safety test. Renewal.
•	03 September 2002	Change in product name.
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•	03 September 2002	Addition of sites for Labelling/Packaging. Transfer of batch release sites.
•	03 September 2002	Variation to change the packaging details.

•	15 March 2002	Variation to change the ingredient specification.
•	11 February 2002	Addition of a Distributor.
•	31 January 2002	Variation to change the finished product characteristics.
•	29 March 2000	Change to finished product specification.
•	29 March 2000	Change to the Manufacturer of Dosage Form.
•	25 February 2000	Change in the name and address of the Marketing Authorisation Holder.
•	23 August 2000	Change in Potency Test Limit.
•	20 October 1999	Extension of product shelf life.
•	22 September 1999	Change in shelf life.
•	17 February 1999	Change in the formulation.
•	11 December 1998	Extension of shelf life
•	15 July 1998	Change of Licence Holder.
•	19 May 1998	Change of Potency Test.