Veterinary Medicines Directorate

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Post Authorisation Assessments

Prosolvin 7.5 mg/ml Solution for Injection
Vm 05653/4158

•	09 April 2019	Tightening of specification limits of the finished product. Deletion of a non-significant specification parameter of the finished product. Deletion of a non-significant specification parameter of the finished product.
•	20 July 2016	Deletion of a manufacturing site of the active substance.
•	06 November 2015	To add an additional manufacturer of the active substance.
•	20 October 2015	Change in the manufacturing process of the finished product.
•	15 April 2013	Grouped variation to add a new specification parameter, tighten the specification limits, delete a non-significant specification parameter, change the storage conditions, and to extend the retest period.
•	28 March 2012	Addition of a pack size in the UK.
•	13 July 2011	Variation to change the batch size (of the finished product).
•	06 April 2011	Change in the shape or dimensions of the container/closure.
•	06 April 2011	Addition of a manufacturer.
•	04 August 2009	Renewal.
•	28 January 2009	Variation to change the active ingredient manufacturer.
•	13 November 2008	Variation to update Part II of the dossier.
•	07 August 2008	Change of the Marketing Authorisation Holder.
•	28 July 2008	Variation to replace a manufacturer responsible for batch release.
•	28 July 2008	Variation to replace a manufacturer of secondary packaging.
•	03 July 2008	Variation to include additional safety warnings under SPC 4.11.
•	10 October 2007	Variation to bring the SPC/Labelling in line with the new legislation. Transfer of the legal category from POM to POM-V.
•	16 March 2006	Batch Control.
•	16 March 2006	Batch Control.
•	26 October 2005	Renewal.
•	01 July 2005	Change of distributor for Northern Ireland.
•	19 May 2005	Addition of a manufacturer and assembler.
•	03 December 2004	Minor corrections/ text changes to the SPC/Labelling.

•	05 March 2004	Renewal.
•	03 July 2001	Addition of a distributor in Northern Ireland.
•	28 June 2000	Variation to update licence particulars.
•	08 May 1998	Variation to modify indications.
•	19 February 1997	Change to withdrawal period.
•	04 January 1996	Change to therapeutic indications.
•	06 October 1995	Change to withdrawal period.