Veterinary Medicines Directorate

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Post Authorisation Assessments

Sedalin 35 mg/ml Oral Gel

Vm 08007/4089

•	02 May 2018	Change in the address of the marketing authorisation holder from Vetoquinol UK Limited, Vetoquinol House, Great Slade, Buckingham Industrial Park, Buckingham, MK18 1PA to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	09 February 2017	Deletion of a non-significant specification parameter of the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 24 to 36 months.
•	12 August 2014	Change to the text in section 4.11 of the SPC and in the product literature.
•	21 October 2010	Change in the test procedure of the finished product.
•	15 July 2009	Change to the primary packaging.
•	16 June 2009	Batch Control.
•	13 May 2009	Batch Control.
•	07 May 2009	Addition of a site of batch release.
•	14 May 2008	Addition of a secondary site of manufacture.
•	14 February 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of legal category from POM to POM-V.
•	22 January 2008	Variation to change the batch release arrangements of the finished product.
•	16 October 2007	Variation to change the name of the active substance manufacturer.
•	13 April 2007	Batch Control.
•	21 March 2006	Variation to change the name of the finished product manufacturer.
•	29 November 2005	Renewal.
•	07 September 2005	Variation to change the address of the importer of final dosage form.
•	19 August 2004	Variation to change the address of the Marketing Authorisation Holder.
•	28 August 2002	Change of importer of the finished product.
•	26 July 2002	Change in batch size of the finished product.
•	26 July 2002	Change in the manufacturing process of the finished product.
•	26 July 2002	Change in the specification of the finished product.
•	26 July 2002	Change in the shape of the packaging container.
•	20 February 2002	Change to the test method of the finished product.

•	21 December 2001	Change of Marketing Authorisation Holder.
•	30 July 2001	Addition of a safety warning.
•	11 April 2001	Renewal.
•	19 January 2001	Change to the QC Procedures.
•	06 December 2000	Change to the active substance manufacturer.
•	25 March 1996	New Marketing Authorisation.