Veterinary Medicines Directorate

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Post Authorisation Assessments

Vecoxan 2.5 mg/ml Oral Suspension

Vm 01708/4648

•	January 2024	Change in the batch size of the finished product.
•	28 November 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	12 January 2023	Updated certificate of suitability from an already approved manufacturer.
•	12 January 2022	Introduction of a new pharmacovigilance system.
•	29 July 2021	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Deletion of Ph. Eur. certificates of suitability for an active substance.
•	08 February 2021	Changes to the labelling and package leaflet.
•	29 September 2020	Change in distributor details. Addition of Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland as a named distributor. Change of MAH, from Eli Lilly & Company Limited, Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, RG24 9NL to MSD Animal Health UK Limited, Walton Manor, Walton, Milton Keynes, Buckinghamshire, MK7 7AJ.
•	10 August 2016	Submission of a new certificate of suitability.
•	10 December 2013	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	27 November 2012	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	02 May 2012	Variation to change the address of the Marketing Authorisation Holder.
•	14 March 2012	Grouped variation to change the distributor details.
•	12 January 2011	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	15 June 2010	Submission of an updated European Pharmacopoeia Certificate of Suitability for an already approved active substance manufacturer.
•	04 August 2009	Variation to make a change to Part II of the Dossier.
•	18 December 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to POM-VPS.

•	22 October 2008	Variation to change the shape or dimensions of the container or closure.
•	06 August 2008	Renewal.
•	11 March 2008	Variation to change the address of the Marketing Authorisation Holder.
•	04 October 2006	Variation to include an additional pack size.
•	05 October 2005	Line Extension.
•	03 June 2005	Change in the composition of the immediate packaging.
•	19 May 2005	Variation to change the manufacturing process of the finished product.
•	19 May 2005	Variation to change the site of manufacture and batch release.
•	09 March 2005	Submission of a European Pharmacopoeia Certificate of Suitability for the active substance manufacturer.
•	17 March 2004	Renewal.
•	19 June 2002	Change of legal category from POM to PML.
•	23 January 2002	Update Licence Particulars.
•	23 January 2002	Change to Safety Warnings.
•	31 Mach 2000	Addition of an assembler of dosage form.
•	08 June 1999	Addition of contraindications and warnings.