Veterinary Medicines Directorate

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Post Authorisation Assessments

Ovidrench S & C 2.5% w/v Oral Suspension for Cattle and Sheep

Vm 50146/4033

•	14 June 2023	Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes.
•	14 June 2023	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	12 June 2023	Changes to the labelling or the package leaflet which shall not be connected with the SPC: – other changes.
•	15 November 2022	Replacement of a Quality Control testing site for the finished product.
•	26 April 2022	Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product. Tightening of specification limits of the immediate packaging of the finished product.
•	26 January 2021	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	23 January 2020	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product.
•	24 July 2019	Change in the name of a manufacturer used in the manufacture of the active substance. Change in the name and/or address of a manufacturer of the finished product, also responsible for batch release.
•	19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 October 2018	Changes to an existing pharmacovigilance system as described in the DDPS. Change of MAH, from Cross Vetpharm Group Ltd, Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght, Dublin 24, Ireland.
•	10 July 2018	Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.
•	15 January 2018	Change in the fill volume of the finished product.
•	02 June 2017	Mock-ups approved.
•	17 May 2017	Change in shape or dimensions of the container or closure (immediate packaging) Deletion of a pack size(s) of the finished product Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	12 April 2017	Submission of an updated Ph. Eur. certificate of suitability.
•	13 January 2017	Deletion of manufacturing sites responsible for batch release and secondary assembly.

•	22 December 2016	Mock-ups approved. Change in Distributor details. From Janssen Animal Health to United Farmers Ltd.
•	16 November 2016	Change in the invented name of the veterinary medicinal product from Ovipec S & C 2.5% w/v Oral Suspension to Ovidrench S & C 2.5% w/v Oral Suspension for Cattle and Sheep.
•	13 July 2016	Minor changes is to improve the homogeneity of the manufacturing suspension and which further ensures the quality of the finished product. Batch size variation, made for commercial reasons and to improve efficiencies during manufacture. Validation of the manufacturing process at the increased batch size Batch scale up to 10-fold compared to the originally approved batch size. Validation of the manufacturing process at the increased batch size. Stability studies on increased batch sizes.
•	15 June 2016	Change in shape or dimensions of the container or closure (immediate packaging). Tightening of specification limits of the finished product. Addition of a new specification parameter of the immediate packaging of the finished product.
•	15 January 2015	Introduction of a new pharmacovigilance system.
•	16 December 2014	Submission of an updated Ph. Eur. Certificate of Suitability for the active substance.
•	29 August 2014	Change of MAH from Eli Lilly and Company Limited, to Cross Vetpharm Group Ltd.
•	12 September 2012	Change of MAH from Janssen Animal Health to Eli Lilly & Company Ltd.
•	07 March 2012	Change of distributor.
•	14 September 2011	Change in the specifications of the finished product.
•	03 June 2011	Changes to the manufacturers of the active substance.
•	02 June 2010	Addition of phrase ‘Do not mix with other products’ to the product literature.
•	19 November 2008	Changes to the SPC and product literature to bring them in line with new legislation.
•	19 November 2009	Change in legal category from PML to POM-VPS.
•	27 February 2008	Change of address of the MAH.
•	14 January 2008	Change in manufacturer of the active substance.
•	31 May 2007	Change to specifications of the finished product.
•	01 February 2007	Renewal
•	30 October 2002	Addition of pack sizes.
•	21 October 2002	Change to label of a pack size.
•	30 May 2002	Addition of an assembler of dosage form (secondary assembly).