



Post Authorisation Assessments

Ovidrench S & C 10% w/v Oral Suspension for Cattle and Sheep

•	11 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.
•	10 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.
•	02 June 2017	Mock-ups approved.
•	15 May 2017	Change in shape or dimensions of the container or closure (immediate packaging) Deletion of a pack sizes 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 10% w/v Oral Suspension to

		Ovidrench S & C 10% w/v Oral Suspension for Cattle and Sheep.
•	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.
•	20 May 2015	Changes to the specification parameters of an excipient.
•	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	Changes to distributor.
•	06 June 2011	Replacements of sites of manufacture of the active substance.
•	02 June 2010	Addition of the statement 'Do not mix with other products' to Section 4.9 of the SPC.
•	11 March 2009	Change in test procedure of the finished product.
•	19 November 2008	Changes to the SPC and product literature to bring into line with new legislation.
•	19 November 2008	Change of legal category from PML to POM-VPS
•	27 February 2008	Change of address of MAH.
•	14 January 2008	Change of the manufacturer of the active substance.
•	31 May 2007	Change in specification of the finished product.
•	01 February 2007	Renewal.
•	30 October 2002	Addition of a pack size.
•	31 May 2002	Change of assembler of finished product.