Veterinary Medicines Directorate

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# Post Authorisation Assessments

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

Vm 50146/4032

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| • | 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.<br>Tightening of specification limits of the immediate packaging of the finished product.<br>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.<br>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.<br>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)<br>Deletion of a pack sizes of the finished product<br>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.<br>Change in Distributor details. From Janssen Animal Health to United Farmers Ltd. |
| • | 16 November 2016 | Change in the invented name of the veterinary medicinal |

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| | | 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).<br>Tightening of specification limits of the finished product.<br>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. |