Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Oxycare Tablets 250 mg

Vm 32742/4032

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| • | 11 August 2022 | Change of MAH: from Animalcare Ltd, 10 Great North Way, York Business Park, Nether Poppleton, York, YO26 6RB, United Kingdom to Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium. |
| • | 12 November 2021 | Changes to the labelling and/or package leaflet. |
| • | 24 May 2019 | -Change in test procedure for the finished product<br>-Change in the dimensions of the pharmaceutical form<br>-Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State.<br>-Deletion of a manufacturing site for the finished product<br>-Replacement of a manufacturing site for the finished product.<br>- Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.<br>-Change in the manufacturing process of the finished product.<br>-Change in the specification parameters for dimension of the finished product.<br>-Changes in the composition (excipients) of the finished product. |
| • | 24 May 2019 | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 27 September 2018 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.<br>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 01 September 2016 | Change to include in-process controls.<br>Change in description of the tablets to include round.<br>Change in description of the tablet core and coated tablet.<br>Change in description of the tablets to be divisible.<br>Removal of reconciliation of the tablets after coating.<br>Change in the shape or dimensions of the pharmaceutical form.<br>Change in imprints of the tablets.<br>Change from sugar coated to film coated tablets.<br>Change to include an additional slugging step during the manufacturing process. |
| • | 26 February 2015 | Change in distributor details. |

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| • | 04 June 2013 | Change to the MAH address. |
| • | 14 February 2012 | Submission of an updated EDQM certificate of suitability for the active substance. |
| • | 13 May 2009 | Change in the manufacturer of the active substance. |
| • | 19 December2008 | Change in the name/address of the MAH. |
| • | 30 September 2008 | Changes to the SPC and product literature to bring them into line with new legislation. |
| • | 01 November 2006 | Renewal |
| • | 14 March 2003 | Renewal |
| • | 19 April 2002 | Deletion of an active substance manufacturer. |
| • | 24 July 2001 | Addition of a manufacturer and assembler of the finished product. |
| • | 21 June 2001 | Change to the ASMF reference number. |
| • | 26 October 2000 | Changes to the formulation. |
| • | 06 December 1999 | Addition of a site of assembly of finished product. |
| • | 18 February 1998 | Changes to the finished product specifications. |
| • | 24 September 1997 | Change on the name of the product. |
| • | 22 June 1997 | Renewal |