Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Oxycare Tablets 250 mg

Vm 32742/4032

•	28 April 2024	Deletion of a manufacturing site for an active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
•	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 -Change in the dimensions of the pharmaceutical form -Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State. -Deletion of a manufacturing site for the finished product -Replacement of a manufacturing site for the finished product. - Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. -Change in the manufacturing process of the finished product. -Change in the specification parameters for dimension of the finished product. -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. Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. 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. Change in description of the tablets to include round. Change in description of the tablet core and coated tablet. Change in description of the tablets to be divisible. Removal of reconciliation of the tablets after coating. Change in the shape or dimensions of the pharmaceutical form. Change in imprints of the tablets. Change from sugar coated to film coated tablets.

		Change to include an additional slugging step during the manufacturing process.
•	26 February 2015	Change in distributor details.
•	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