Veterinary Medicines Directorate

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Post Authorisation Assessments

Xylacare 2% w/v Solution for Injection

Vm 32742/4036

•	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.
•	29 July 2022	Substantial changes in the updated version of the ASMF.
•	01 October 2019	Increase in batch size of the active substance used in the manufacturing process of the active substance. Tightening of specification limits of an active substance used in the manufacturing process of the active substance. Change in the manufacturer of a starting material. Minor change to the restricted part of an Active Substance Master File.
•	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.
•	03 November 2016	Change in test procedure for the active substance. Replacement of a site where batch control/testing takes place. Change in the manufacturing process of the active substance. Change in the re-test/storage period of the active substance. Change in the manufacturing process of the active substance. Replacement of a manufacturing site of the finished product. Addition of a manufacturer of the active substance.
•	26 February 2015	Change in distributor details.
•	21 June 2013	Change to the MA holder address.
•	09 December 2009	Updates to the SPC and product literature.
•	11 September 2008	Updates to bring the SPC and product literature in line with new regulations and to change the distribution category from POM to POM-V.
•	13 March 2007	Change to the test procedure for the finished product.
•	06 March 2006	Renewal.
•	05 November 2004	Change to comply with horse passport legislation.