Veterinary Medicines Directorate

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Post Authorisation Assessments

Alfaxan 10 mg/ml Solution for Injection for Dogs and Cats

Vm 25296/4000

•	17 June 2021	Replacement of a manufacturer responsible for batch release of the finished product.
•	30 December 2020	Update of SPC and package leaflet text as assessed under Regulation 1901/2006.
•	08 June 2020	Change in 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.
•	16 April 2020	Reduction of the shelf life of the finished product as packaged for sale from 5 years to 2 years. Addition of a specification parameter of the finished product.
•	11 February 2019	Change in RMS from UK to IE.
•	06 December 2018	Increase in batch size (300-720L) of the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 36 months to 5 years.
•	09 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	03 October 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	19 April 2017	Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions. Increase in batch size of the finished product.
•	21 September 2016	Up to 10-fold increase in batch size of the active substance compared to the currently approved batch size. Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release. Change in the address of the Marketing Authorisation Holder. Deletion of manufacturing site for a manufacturer of batch release.
•	08 July 2015	Repeat Use procedure – UK RMS
•	21 April 2015	Changes to the SPC and product literature.
•	05 September 2013	Addition of a batch release site
•	13 June 2013	Introduction of a new pharmacovigilance system.
•	07 March 2013	Minor changes to the manufacturing process. Change

		in the address of the Marketing Authorisation Holder. Replacement of a manufacturer responsible for batch release. Replacement of a secondary packaging site for the finished product.
•	30 January 2013	To change the distributor from Vetoquinol (UK) Limited to Jurox (UK) Limited.
•	30 July 2012	Renewal.
•	13 May 2011	To change the shelf life of the finished product from 30 months to 36 months.
•	29 April 2009	To change the address of Marketing Authorisation Holder
•	28 May 2008	New MRP- UK as RMS
•	10 January 2007	Variation to add an alternative manufacturer for step 2 of the 6-step process for the active substance.
•	10 January 2007	Variation to add an alternative manufacturer of the starting material for synthesis of the active substance.
•	10 January 2007	Variation to add an alternative manufacturer for step 1 of the 6-step process for the active substance.