Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 42058/4214

•	April 2024	Change in the pharmacovigilance system master file (PSMF) location. Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
•	21 September 2023	Change of importer and batch release arrangements.
•	18 August 2023	Introduction of the Zoetis DDPS. (GB)
•	14 August 2023	Change of Legal Entity from Jurox (UK) Limited, Second Floor, Richmond House, 105 High Street, Crawley, West Sussex, RH10 1DD to Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP.
•	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.