Veterinary Medicines Directorate

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

Post Authorisation Assessments

Alfaxan Multidose 10 mg/ml Solution for Injection for Dogs, Cats and Pet Rabbits

Vm 42058/4218

•	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). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	24 August 2023	Deletion of a manufacturer responsible for batch release.
•	23 August 2023	Introduction of the Zoetis DDPS.
•	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.
•	25 May 2023	Change to importer, batch release arrangements and quality control testing of the finished product: - Replacement or addition of a manufacturer responsible for importation and/or batch release - Other changes.
•	19 April 2023	Addition of a named distributor: Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP, United Kingdom.
•	03 March 2023	Unlimited renewal
•	24 January 2023	Change to batch control arrangements and quality testing (replacement or addition of a site) for a finished product. Changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place. Changes to the quality part of the dossier: Deletion of - a manufacturing site for an active substance, intermediate. Minor changes to an approved test procedure for the immediate packaging of the finished product.
•	18 January 2023	Additional site of batch release for Northern Ireland.
•	05 October 2022	Update of address of the external laboratory for sterility testing. Update of address of the external laboratory for microbial testing. Deletion of a manufacturing site for the intermediate of the active substance.

		Minor changes to an approved test for the immediate packaging of the finished product.
•	02 August 2022	Minor changes to the manufacturing process of the finished product.
•	17 June 2021	Replacement of a manufacturer responsible for batch release of the finished product.
•	12 May 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Change in the name/address of a manufacturer of an intermediate used in the manufacture of the active substance. Tightening of specification limits of the finished product.
•	30 December 2020	Update of SPC and package leaflet text as assessed under Regulation 1901/2006.
•	05 August 2020	Change in shape or dimensions of the container or closure (immediate packaging). Addition of a specification parameter of the finished product.
•	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.
•	11 February 2019	Change in RMS from UK to IE.