



Post Authorisation Assessments

Alfaxan Multidose 10 mg/ml Solution for Injection for Dogs and Cats Vm 42058/4221

•	09 February 2024	Unlimited renewal.
•	21 September 2023	Change of importer and batch release arrangements.
•	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.
•	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.
•	20 October 2021	Repeat use to add 7 member states.
•	06 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.