



Post Authorisation Assessments

Alfaxan 10 mg/ml Solution for Injection for Dogs, Cats and Pet Rabbits Vm 42058/4217

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| • | 28 November 2023 | Removal of the local representative. |
| • | 25 August 2023 | Deletion of a manufacturer responsible for batch release. |
| • | 21 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. |
| • | 26 May 2023 | Addition of Distributor: Zoetis UK Limited, 1st Floor, Birchwood Building, Springfield Drive, Leatherhead, Surrey, KT22 7LP, United Kingdom. Change to importer, batch release arrangements of the finished product: - Replacement or addition of a manufacturer responsible for importation and/or batch release. |
| • | 13 October 2022 | Change in address of sterility testing site for the finished product. Change in address of the site for microbial testing of the active substance. Update to the identification method listed in the stopper specification for the finished product. |
| • | 04 February 2022 | Admin Renewal |
| • | 11 January 2022 | Change in the address of a manufacturer of active substance used in the manufacture of the active substance. Deletion of manufacturing site for an active substance. |
| • | 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. |
| • | 20 November 2019 | Reduction of the shelf life of the finished product as packaged for sale from 60 months to 24 months. Addition of a specification parameter of the finished product. |
| • | 20 August 2019 | Changes in the SPC, Labelling or Package Leaflet of a medicinal product intended to implement the outcome of a procedure concerning PSUR. |
| • | 30 August 2018 | Change in the safety database of an existing pharmacovigilance system as described in the DDPS. |
| • | 26 March 2018 | Increase in batch size (including batch size range) of the |

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| | | finished product. |
| • | 04 December 2017 | Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. |