



## Post Authorisation Assessments

### Alfaxan Multidose 10 mg/ml Solution for Injection for Dogs and Cats Vm 42058/5216

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| 22 July 2025      | Change in the shelf-life of the finished product.   |
| 13 March 2025     | Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).<br>Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI).   |
| 05 March 2025     | Change in batch size of finished active ingredient. (NI).   |
| 05 February 2025  | Batch size range of active substance updated. (GB).   |
| 22 December 2024  | Alignment of the product information with version 9.0* of the QRD templates.  |
| 22 December 2024  | Change to the address of a quality control testing site of the active substance.<br>Change to the address of a quality control testing site of the active substance.<br>Deletion of a manufacturing site for an intermediate of the active substance.<br>Minor changes to an approved test procedure for the immediate packaging of the finished product. (GB & NI) |
| 30 December 2024  | Deletion of a site of batch release. (NI)   |
| 14 November 2024  | Editorial update to name of a site used for quality control (NI).   |
| 09 October 2024   | Editorial update to name of a site used for quality control. (GB)   |
| 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.<br>Update of address of the external laboratory for microbial testing.<br>Deletion of a manufacturing site for the intermediate of the active substance.<br>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   |

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|                  | <p>contact with the finished product formulation.</p> <p>Change in the name/address of a manufacturer of an intermediate used in the manufacture of the active substance.</p> <p>Tightening of specification limits of the finished product.</p> |
| 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   | <p>Change in shape or dimensions of the container or closure (immediate packaging).</p> <p>Addition of a specification parameter of the finished product.</p>  |
| 08 June 2020     | <p>Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.</p> <p>Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.</p>                                 |
| 11 February 2019 | Change in RMS from UK to IE.   |