



Post Authorisation Assessments

Ataxxa 200 mg/40 mg Spot-on Solution for Dogs up to 4 kg Vm 01656/5034

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| 25 September 2025 | Deletion of distributors Centaur Services Limited, Henry Schein UK Holdings Limited, Movianto UK Limited, National Veterinary Services Limited, Potter Logistics Limited, Unidrug Distribution Group Limited and replace with KRKA UK Ltd. |
| 10 September 2025 | Change in the name or address or contact details of a manufacturer or importer of the finished product (including batch release or quality control testing sites). Deletion of a specification parameter from the active substance specification. Deletion of a manufacturing site for quality control testing of the active substance. Deletion of a manufacturing site for an active substance. |
| 16 April 2025 | Change in the holding time of an intermediate or bulk product. |
| 12 December 2024 | Minor change in the manufacturing process of the finished product. |
| 12 January 2024 | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| 06 November 2023 | Amendments to relevant sections of the SPC following the endorsement by the European Commission of the CVMP Opinion on the Article 83 referral regarding VMPs containing N-methyl pyrrolidone (NMP) as an excipient. |
| 06 April 2023 | Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid medicinal product following assessment of the same change for the reference product. One-off alignment of the product information with version 9.0* of the QRD templates. |
| 30 March 2023 | Update for an approved in process test. |
| 03 February 2023 | Change to comply with an update of the relevant monograph of the Ph. Eur. |
| 18 November 2021 | Changes to the labelling and/or package leaflet. |
| 15 October 2021 | Addition of a new therapeutic indication. |
| 15 October 2021 | Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product. |
| 16 June 2021 | Minor change in the manufacturing process of the finished product. Change to in-process tests or limits applied during the manufacture of the finished product. |

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| 08 January 2021 | Renewal - UK as CMS. |
| 11 November 2020 | Minor changes to an approved test procedure of the finished product. |
| 13 March 2020 | Update to indications section of the SPC. |
| 03 March 2020 | Minor change in the manufacturing process of the finished product. Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. |
| 29 August 2019 | To change a local representative from Krka UK Ltd, 20-22 Bedford Row, London, WC1R 4JS to KRKA UK Ltd, United Kingdom. |
| 11 June 2019 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| 18 December 2018 | Change to in-process tests or limits applied during the manufacture of the finished product Minor changes to an approved test procedure of the finished product |
| 20 June 2018 | Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years. |
| 27 February 2018 | Change in the RMS from UK to IE. |
| 05 December 2017 | Increase in batch size from 10Kg-100kg to up to 150kg used in the manufacturing process of the active substance. Change in the manufacturer used in the manufacturing process of the active where no Ph. Eur. Certificate of Suitability is part of the approved dossier. Extension of a re-test period of the active substance. |