



Post Authorisation Assessments

Ataxxa 1250 mg/250 mg Spot-on Solution for Dogs over 10 kg up to 25 kg Vm 01656/3036

•	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.
•	November 2023	Minor changes to an approved test procedure for an in-process test for the finished product.
•	12 June 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State.
•	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.
•	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.
•	07 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	<p>Increase in batch size from 10Kg-100kg to up to 150kg used in the manufacturing process of the active substance.</p> <p>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.</p> <p>Extension of a re-test period of the active substance.</p>