Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Fortekor 2.5 mg Tablets for Cats and Dogs

Vm 52127/5073

•	18 March 2025	Change in legal entity from Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood, Business Park, Hook, RG27 9XA, United Kingdom to Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, D-27472, Cuxhaven, Germany.
•	04 May 2024	Addition of 'diarrhoea and anorexia' to the product literature.
•	23 April 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes to an approved test procedure for the finished product.
•	12 March 2024	Changes to the labelling not connected with the SPC.
•	31 August 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
•	01 February 2022	Change in the manufacturing process of the finished product.
•	28 January 2022	Deletion of a manufacturing site for an active substance.
•	01 December 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Changes in the manufacturing process of the finished product. Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	14 April 2021	Change to part of the (primary) packaging material not in contact with the finished product formulation.

		Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product.
•	03 February 2021	Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Deletion of a non-significant specification parameter of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product.
•	21 December 2020	Replacement to a test procedure for the finished product.
•	09 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
•	11 June 2020	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure.
•	03 September 2019	Addition of a site where batch control/testing takes place.
•	05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	27 December 2018	Change in the name of a manufacturer used in the manufacture of the active substance.
•	01 May 2018	Change in the name of a supplier of intermediate used in the manufacture of the active substance. Change in the name of a supplier of intermediate used in the manufacture of the active substance. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

•	07 February 2018	Change in the RMS from UK to IE.
•	22 June 2017	Change in the name of a manufacturer of the active substance.
•	07 March 2017	Introduction of a new pharmacovigilance system.
•	05 September 2016	Addition of a test and limits for to the active substance specification.
•	05 September 2016	Addition of a manufacturer of the starting material. Addition of Ph. Eur. test method and limit Addition of a Ph. Eur. test method Addition of a Ph. Eur. test method
•	15 August 2016	Change in the name of a manufacturer of the finished product including manufacturer responsible for batch release
•	16 March 2016	Change in distributor details Change in legal entity
•	13 August 2015	Addition of a new manufacturer of the starting material. Re-definition of a starting material used in the manufacture of the active substance.
•	30 June 2014	Change of name and address for an active substance manufacturer, deletion of active substance manufacturer and addition of two sites for quality control testing.
•	25 April 2014	Changes in the specification parameters and/or limits of the finished product.
•	27 March 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	05 March 2014	Changes to the package leaflet which do not affect the SPC.
•	23 August 2012	To add a manufacturer with consequential changes to protocol.
•	13 July 2012	Addition of a site responsible for primary and secondary packaging.
•	13 July 2012	Replacement of a site responsible for primary and secondary packaging.
•	12 July 2012	Update of testing monograph for active substance, several changes including changes in test procedures, tightening of specification limits, replacement of a test method, addition of new specification parameters and addition of a new specification parameter as a result of a safety or quality issue.
•	12 July 2012	Update of testing monograph for active substance, several changes to a preparation protocol and addition of an in-process control. Addition of packaging sites, batch size changes for compounds.
•	22 February 2012	Changes to the specification parameters of an excipient.
•	22 February 2012	Changes in the specification parameters and/or limits of the finished product. (5 mg product only).
•	21 November	Change in the test procedure of the finished product. Change in the specifications of the finished product.

•	16 September 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
•	14 December 2009	Renewal procedure – UK as RMS.
•	30 June 2008	Change in active/intermediate batch size, change in name and address of manufacturer of active substance.
•	17 June 2008	Simple corrections/text changes/layout to SPC and product literature.
•	22 October 2007	Change of Marketing Authorisation Holder name/address.
•	08 June 2007	Minor changes in manufacturing process of active.
•	12 January 2007	Change to pack size of finished product.
•	08 June 2005	Addition of a non-food producing target species.
•	25 April 2005	Change of a test method.
•	15 April 2005	Change in the shelf life after first opening.
•	20 August 2003	Change in the shelf life of the finished product.
•	24 July 2003	Change of test methods used in the active substance manufacturing process.