Veterinary Medicines Directorate

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Post Authorisation Assessments

Fortekor Flavour 5 mg Tablets for Cats and Dogs

Vm 52127/3036

21 May 2026	Addition of contact details to report suspected adverse reactions for the Marketing Authorisation Holder.
02 June 2025	Change the named distributor from Elanco Europe Ltd. to Elanco UK AH Ltd. Change of Marketing Authorisation Holder 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, 27472 Cuxhaven, Germany.
18 January 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
06 July 2024	Addition of rare adverse events - diarrhoea and vomiting.
10 July 2024	Additional adverse reactions in dogs added.
November 2023	Other changes - Editorial updates to Part II of the dossier.
31 August 2023	One-off alignment of the product information with version 9.0* of the QRD templates.
28 January 2022	Deletion of a manufacturing site for an active substance.
16 April 2021	Changes in the specification parameters and/or limits of the immediate packaging of the finished product. Changes in the specification parameters and/or limits of the immediate packaging of the finished product. Changes in the specification parameters and/or limits of the immediate packaging of the finished product. Changes in the specification parameters and/or limits of the immediate packaging of the finished product. Changes 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.
10 February 2021	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.

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30 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 an intermediate used in the manufacturing process 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
03 August 2015	Addition of a new manufacturer of a starting material. Re-definition of a starting material used in the manufacture of the active substance.
14 May 2015	Renewal – UK as RMS.
01 July 2014	Change of name of a manufacturer of a starting material.
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	Change in the specification parameters and/or limits of an excipient.
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.
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.
11 May 2012	Update of SPC and product literature in order to implement the outcome of an Article 34 referral.
22 February 2012	Changes in the test procedure of the finished product. (5 mg product only).
22 February 2012	Changes in the specification parameters and/or limits of the finished product. (5 mg product only).
16 September 2011	Changes to an existing pharmacovigilance system as described in the DDPS.
14 October 2010	To change the product name from **Benazepril Hydrochloride Novartis 5 mg Tablets for Dogs** to **Fortekor Flavour 5 mg Tablets for Dogs**
23 July 2010	Change in the specification parameters used in the manufacturing process of the active substance