

Post Authorisation Assessments

Fuselieve 1 mg/g + 5 mg/g Gel for Dogs

Vm 02000/4405

31 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
20 March 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
12 February 2025	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB)
22 January 2025	One-off alignment of the product information with version 9.0* of the QRD templates.
04 May 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (NI)
04 May 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer. (GB)
23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex (NI)
17 November 2023	Editorial changes relating to updating the method of analysis of the finished product.
03 February 2023	Change in dimensions of the immediate packaging of the finished product.
20 September 2022	Change in dimensions of the immediate packaging of the finished product.
30 September 2021	Renewal – UK as CMS
27 October 2020	Addition of a secondary packaging site of the finished product.
11 September 2019	Minor changes to an approved test procedure of the finished product. Tightening of specification limits of an excipient.
26 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
26 June 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
19 June 2019	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
25 March 2019	Repeat use application to add 1 new member state.
21 March 2019	Change in RMS from UK to IE.
17 January 2019	Change in the invented name of the veterinary medicinal product from Inflabac to Fuselieve.
26 November 2018	Change in distributor details. From Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay, Industrial Estate, Corby, Northamptonshire, NN18 9EX to CVS UK Ltd., CVS House, Owen Road,

	Diss, Norfolk, 1P22 4ER, United Kingdom.
10 April 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.