



Post Authorisation Assessments

Fuselieve 1 mg/g + 5 mg/g Gel for Dogs Vm 02000/4405

•	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, IP22 4ER, United Kingdom.
•	10 April 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

