



## Post Authorisation Assessments

### Alfamed Fipronil 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs Vm 17902/4060

•	20 July 2021	Change in shape or dimensions of the container or closure (immediate packaging).
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
•	14 September 2018	Change in RMS from UK to FR.
•	30 November 2017	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products.
•	03 August 2017	Change in the invented name of the veterinary medicinal product from Fiproline 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs to Alfamed Fipronil 2.5 mg/ml Cutaneous Spray, Solution for Cats and Dogs (UK) Change in the invented name of the veterinary medicinal product from Exil Fipralone 2.5mg/ml Cutaneous Spray, Solution for Cats and Dogs to Fipralone 2.5 mg/ml cutaneous spray, solution for cats and dogs (NL)
•	14 June 2017	Change in the name and address of a manufacturer used in the manufacture of the active substance. Addition of a manufacturer of the active substance.
•	05 January 2016	Change in shape or dimensions of the container or closure (immediate packaging) x6
•	21 October 2015	To add an additional site of purification for the active substance.
•	09 July 2015	Change to the invented name of the medicinal product in France, Italy and The Netherlands only.
•	19 January 2015	Addition of an active substance manufacturer. Changes to the specification limits.
•	14 March 2014	Change in dimension of immediate packaging.
•	04 December 2013	Renewal procedure.
•	27 September 2012	Minor changes to the purification process of the active substance. Deletion of a non-specific specification parameter in the manufacture of the active substance. Increase in batch size range of active substance.
•	01 August 2012	Change of legal entity to POM-V.
•	11 August 2011	Grouped variation to increase the batch size of the finished product.
•	11 August 2011	Grouped variation to change the shelf life of the veterinary

		medicinal product as packaged for sale from 2 years to 3 years.
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