



## Post Authorisation Assessments

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

Vm 17902/5021

05 January 2026	Deletion of one of the authorised bulk or final containers of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form.
19 March 2025	Change in shape or dimensions of the container or closure (immediate packaging):- The change in shape or dimensions concerns a fundamental part of the packaging material, which may have a significant impact on the delivery, use, safety or stability of the finished product.
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.