Veterinary Medicines Directorate

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Post Authorisation Assessments

Alfamed Fipronil 134 mg Spot-on Solution for Medium Dogs

Vm 17902/4061

•	27 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.
•	11 April 2018	Increase in the shelf-life of the finished product as packaged for sale, from 24 months to 36 months for the thermoformed pipettes.
•	30 January 2018	Deletion of a manufacturing site of the finished product.
•	03 August 2017	Change in the invented name of the veterinary medicinal product from Fiproline 134 mg Spot-on Solution for Medium Dogs to Alfamed Fipronil 134 mg Spot-on Solution for Medium Dogs (UK) Change in the invented name of the veterinary medicinal product from Exil Fipralone 134 mg Spot-on Solution for Medium Dogs to Fipralone 134 mg Spot-on Solution for Medium 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.
•	09 December 2016	Minor change in the manufacturing process of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product
•	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.
•	23 September 2014	Change to an in-process test applied during the manufacture of the finished product.
•	04 July 2014	Renewal procedure – UK as RMS.
•	25 April 2014	Addition of packaging site.
•	27 September 2012	Deletion of a non-significant parameter used in the manufacturing process of the active substance. Increase in the batch size range of the active substance. Minor change to the purification process of the active substance.
•	31 August 2012	Change in the primary packaging not in contact with the finished product. Addition of an individual blister for each

		pipette.
•	01 August 2012	Submission of mock-ups for approval.
•	11 August 2011	To change the shape or dimensions of the container or closure (immediate packaging).
•	11 August 2011	To change the immediate packaging of the finished product.
•	29 June 2011	To provide mock ups for previously un-marketed pack sizes.
•	15 June 2011	To submit mock-ups for the presentations of boxes of 3 and 6 pipettes.
•	23 July 2010	To increase the shelf life from 18 months to 24 months.
•	02 June 2010	To improve and clarify shapes of pipettes.
•	05 January 2010	To add a manufacturing site for the secondary packaging, in the UK only.
•	29 December 2009	To remove the text “To be supplied on veterinary prescription only” from the packaging material.
•	15 December 2009	Change of distributor.