Veterinary Medicines Directorate

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Post Authorisation Assessments

Fleasolve 67 mg Spot-on Solution for Small Dogs

Vm 49507/5001

09 July 2026	Deletion of a non-significant in-process test. Change to the batch control sites for the finished product.
08 March 2026	Minor change to the labelling. Minor change to the labelling.
09 December 2025	Addition of a batch control site.
14 August 2025	Change in the address of the manufacturer responsible for batch release. Change in the address of the MAH - Deletion of Laboratory E12 from MAH address.
23 February 2024	Deletion of a manufacturing site(s) for an active substance.
23 February 2024	Administrative changes: - Change in distributor details. Addition of a new distributor of the finished product. Replacement of a manufacturing site for part or all of the manufacturing process of the finished product.
23 February 2024	Site of batch control testing replaced with 2 new sites for batch control testing of the finished product. Site of primary packaging replaced with a new primary packaging site for the finished product. Site of secondary packaging replaced with a new secondary packaging site for the finished product.
10 November 2023	Change in immediate packaging of the finished product. Minor change in the manufacturing process of the finished product.
31 July 2023	Changes to the labelling or the package leaflet which shall not be connected with the SPC. Design change - QRD not impacted.
28 April 2023	Replacement of a manufacturer responsible for batch release of the finished product.
09 February 2023	Changes in the name or address or contact details of a qualified person for pharmacovigilance.
25 July 2022	Change of product name from Fipralone to Fleasolve.
18 July 2022	Change of MAH, from Alfamed to Naqua Ltd.
29 August 2018	Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
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.
21 February 2018	National Renewal
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
04 February 2016	Mock-ups Approved
18 November 2015	Addition of a secondary packaging site.
21 October 2015	To add an additional site of purification
23 September 2015	Change in the name of product, from ‘Alfamed Fipronil’ to ‘Fipralone’.
12 January 2015	Addition of a manufacturer for the active substance. Change in the specification limits.
23 September 2014	Change to an in-process test applied during the manufacture of the finished product.
22 January 2014	Change of legal category from NFA-VPS to AVM-GSL. Change to the invented name of the veterinary medicinal product.