Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Fleasolve 402 mg Spot-on Solution for Very Large Dogs

Vm 49507/4006

•	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 in the 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.
•	01 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 for the active substance.
•	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.