



Post Authorisation Assessments

Fleasolve 268 mg Spot-on Solution for Large Dogs

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| • | 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 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. |