Veterinary Medicines Directorate

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Post Authorisation Assessments

Fipronil Spot-on Solution by Virbac 134 mg for Medium Dogs

Vm 05653/3020

•	28 June 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	14 March 2019	Change in the invented name of the veterinary medicinal product from Effipro Spot-On to Fipronil Spot-On in the UK.
•	16 November 2018	Changes to the labelling and package leaflet.
•	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 manufacturing site for the finished product.
•	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.
•	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.
•	18 July 2014	Renewal procedure – UK as RMS.
•	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.
•	02 September 2011	To add pictures under the heading 'Method of administration' in the SPC and packaging explaining

		the use of the different pipettes.
•	15 April 2011	To change the shelf-life of the finished product from 18 to 24 months.
•	14 January 2011	To add a new pipette with a new shape.
•	23 September 2010	Change in immediate packaging of the finished product.
•	07 September 2010	Approval of mock-up for authorised pack size (new pack size to UK)
•	02 June 2010	Clarification regarding the form of the used pipettes.
•	20 January 2010	To remove the text "To be supplied on veterinary prescription only" from the packaging material.