



Post Authorisation Assessments

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

Vm 05653/3020

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| • | 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. |

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| • | 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. |