Veterinary Medicines Directorate

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Post Authorisation Assessments

Fiproxile 134 mg/1200 mg Spot-on Solution for Medium Dogs

Vm 17902/5027

20 March 2024	Change in the packaging material of bulk product not in contact with the bulk product formulation. (NI)
16 November 2023	Minor change to an approved test procedure for the finished product.
10 January 2023	Addition of presentation modification of over-blister. (GB)
10 January 2023	Minor change to an approved test procedure for the finished product.
23 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
24 February 2020	Deletion of manufacturing site for an active substance.
14 August 2019	Minor change in the manufacturing process of the finished product. Change in the name of the manufacturer of the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Increase in the shelf-life of the finished product as packaged for sale, from 2 to 3 years. Change in the specification limits of the finished product. Change in the specification limits of the finished product.
28 March 2019	Renewal – UK as CMS
12 October 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. monograph 2869.
10 September 2018	Change in RMS from UK to FR.
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.
16 March 2017	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.
18 April 2016	Change in the invented name of the product from Fiprotix to Fipratix in Italy only.
28 January 2016	Change in test procedure of the finished product. Addition of a manufacturing site for the active substance.

10 December 2015	Changes to the therapeutic indications. Change in the (invented) name of the medicinal product in Spain.
18 March 2015	Update to the finished product specification.
12 January 2015	Change in the specification limits of the finished product.
02 October 2014	To change the invented name of the medicinal product from ‘Fiperm’, to ‘Fiproxile’ in the UK, to ‘Perfikan’ in France and to ‘Fiprotix’ in the Netherlands, Italy and Spain.
19 September 2014	Change in the quantitative composition, with respect to excipients, of the finished product.