



Post Authorisation Assessments

Bob Martin Fipronil 402 mg Spot-on Solution for Extra Large Dogs Vm 52797/5008

•	July 2021	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
•	29 May 2020	Change of MAH, from Bob Martin (UK), Wemberham Lane, Yatton, Somerset, BS49 4BS, United Kingdom to Pets Choice Limited, Brentwood House, Lower Philips Road, Whitebirk Industrial Estate, Blackburn, Lancashire, BB1 5UD, United Kingdom.
•	21 January 2020	RMS change from UK to FR
•	28 November 2017	Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used). Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier: Storage Conditions. Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance.
•	02 February 2017	Renewal – UK as RMS
•	22 June 2016	Change in the specification limits of a reagent used in the manufacturing process of an active substance. Changes to an existing pharmacovigilance system as described in the DDPS. Deletion of a manufacturing site.
•	8 th February 2012	Change in test procedure for the finished product
•	14 th June 2013	Changes to an existing pharmacovigilance system as described in the DDPS
•	1 st November 2013	Changes to the labelling or package leaflet which are not connected to the SPC
•	11 th December 2013	Change in the (invented) name of the medicinal product
•	27 th June 2014	Change in the (invented) name of the medicinal product