



Post Authorisation Assessments

Fiprotec 402 mg Spot-On Solution for Extra Large Dogs Vm 41941/4004

•	22 February 2022	Changes to the labelling and/or package leaflet.
•	20 May 2020	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Addition of a manufacturer of the active substance.
•	08 August 2019	Renewal- UK as CMS.
•	24 July 2018	Change in RMS from UK to NL.
•	14 June 2018	Change of distributor from Beaphar B.V., Drostenkamp 3, 8101 BX Raalte, The Netherlands to Beaphar UK Ltd, Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD
•	29 March 2018	Change in type of container for the finished product. Change in type of container for the finished product. Change in the number of units (e.g. tablets, ampoules, etc.) in a pack within the range of the currently approved pack sizes of the finished product. Changes to the package leaflet.
•	09 February 2018	Increase in batch size (including batch size range*) of the finished product. Addition of a manufacturer responsible for importation batch release including batch control/testing. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	28 June 2016	Change in the SPC, labelling or package leaflet due to new data.
•	04 June 2015	Change in distribution category.
•	20 May 2015	Updates to SPC and product labelling, including the removal of flea allergy dermatitis claim. Change in pack size of the finished product.