Veterinary Medicines Directorate

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Post Authorisation Assessments

Drontal Oral Suspension for Puppies
Febantel 15 mg/ml / Pyrantel 5 mg/ml
Vm 08007/3001

•	20 July 2024	Change in immediate packaging of the finished product. Minor change in the manufacturing process of an aqueous oral suspension. Change in test procedure for active substance. Change in test procedure for an excipient. Change in test procedure for the finished product. Change in test procedure for the finished product. Addition of a manufacturing site performing micronisation. Change in the specification parameters and/or limits of an active substance. Change in the specification parameters and/or limits of the finished product. Change in the specification parameters and/or limits of the immediate packaging of the finished product. Addition of a manufacturing site for all of the manufacturing process of the finished product.
•	20 July 2024	Change to batch control arrangements and quality testing (replacement or addition of a site) for a finished product. Change to in-process tests or limits applied during the manufacture of the finished product. Minor changes to an approved test procedure for the finished product. Addition of a primary packaging site of a non-sterile finished product. Addition of a secondary packaging site of a finished product.
•	20 July 2024	Addition of a manufacturer responsible for batch release.
•	15 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	14 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.

•	28 September 2021	Introduction of a new pharmacovigilance system.
•	05 November 2020	Change of MAH from Bayer Animal Health GmbH, 51368 Leverkusen, Germany to Vetoquinol UK Limited, Steadings Barn, Pury Hill Business Park, Nr. Alderton, Towcester, Northamptonshire, NN12 7LS.
•	09 June 2020	Change of MAH, from Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD to Bayer Animal Health GmbH, 51368 Leverkusen, Germany.
•	26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	18 September 2018	Change in distributor details from Bayer plc, Animal Health Division, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green park, Reading, Berkshire, RG2 6AD.
•	18 May 2018	Change in RMS from UK to IE.
•	05 January 2018	Change in the address of the marketing authorisation holder from Bayer plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA to Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 May 2016	Changes to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH
•	16 April 2014	Change in MAH.
•	03 July 2013	Renewal.
•	28 February 2013	Addition of a secondary packaging site for the finished product.
•	16 February 2011	Variation to change the distributor.
•	19 November 2010	To change the address of the MAH in France.
•	10 March 2010	Simple text changes to the Product Literature.
•	30 June 2008	Mutual Recognition Procedure. UK as RMS.
•	04 October 2007	Renewal.
•	04 July 2007	Change to the SPC/Labelling to bring them in line with the Veterinary Regulations, 2005. Transfer of the legal category from PML to NFA-VPS.
•	04 October 2006	Update DMF.
•	10 November 2005	Change in the active substance specifications.
•	15 September 2005	Extension of the active substance retest period.
•	25 May 2005	Shelf life extension.
•	18 February 2005	Variation to update the current finished product specification.
•	03 February 2004	Variation to change the Marketing Authorisation Holder.
•	17 July 2003	Renewal.
•	29 March 2001	Change of active substance manufacturer.