



Post Authorisation Assessments

Drontal Plus Flavour Tablets for Dogs Vm 08007/4168

• 19 October 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.
• 09 June 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
• 18 September 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer.
• 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.
• 05 May 2017	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.
• 20 February 2017	Changes to SPC & Product literature to implement the outcome of a procedure following PSUR.
• 27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
• 8 December 2015	Addition of a secondary packaging site
• 07 February 2014	Change in the immediate packaging of the finished product.
• 03 February 2014	Change in the specification parameters of an active substance.
• 28 November 2013	Renewal.
• 31 July 2013	Change to the active substance specification.
• 29 June 2012	Harmonisation variation.
• 27 July 2011	Change in the pack size of the finished product.
• 27 July 2011	To change the name of the veterinary medicinal product from Dog Wormer Tablets to Drontal Plus Flavour Tablets.
• 08 March 2011	Change of distributor.

•	02 March 2011	To update the Active Substance Master File.
•	02 February 2011	Variation to update dossier.
•	24 March 2010	To add a flavour component to the product and to update the Quality dossier for the amended product i.e for the flavoured variant
•	10 March 2010	To remove the wording 'To be supplied only on Veterinary Prescription' from the product literature.