Veterinary Medicines Directorate

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Post Authorisation Assessments

Drontal Cat XL Film-coated Tablets

•	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.
•	03 May 2018	Change in the SPC, Labelling and Package Leaflet for products intended to implement the outcome of a procedure concerning a PSUR.
•	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.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	16 August 2013	Change in immediate packaging of the finished product
•	31 July 2013	Changes to specification parameters of an active substance
•	12 February 2013	Update and re-wording of text on packaging
•	20 December 2011	Changes to the labelling/package leaflet that are not connected to the SPC
•	14 April 2011	Submission of an updated Active Substance Master File (ASMF)
•	09 February 2011	Change of distributor
•	23 February 2010	Change to in-process tests/limits applied during manufacture of the finished product

•	05 February 2010	Change of batch size Change of tablet dimensions
•	21 July 2009	Renewal
•	07 March 2007	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 July 2005	Increase in shelf life from 36 months to 48 months
•	16 June 2005	Batch control
•	26 November 2004	Harmonisation of SPC
•	04 October 2004	Change of specification of finished product