



Post Authorisation Assessments

Drontal Plus XL Flavour Tablets for Dogs

•	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
•	03 March 2014	Change in the specification parameters of an active substance.
•	28 November 2013	Renewal.
•	18 April 2011	Update of active substance data.
•	02 March 2011	Change of Distributor.
•	04 November 2010	To harmonise the SPC and product literature with Ireland.
•	11 November 2009	To include ½ tablet dosing on the SPC and Package Leaflet for 17.5 kg dogs.
•	23 June 2009	Change of product name from BIG WORMER TABLETS to DRONTAL PLUS XL FLAVOUR TABLETS
•	16 April 2009	To change the licensed pack sizes from 2, 10, 20, 50 and 100 tablets to 2, 8, 48 and 96
•	14 January 2009	To include a flavour component