



Post Authorisation Assessments

Drontal Plus XL Flavour Tablets for Dogs

Vm 08007/4169

10 October 2025	<p>Change in the composition of the immediate packaging for a solid pharmaceutical form for a finished product.</p> <p>Down scaling of the batch size of the finished product at Europhartech.</p> <p>Addition of a new specification parameter to the specification of the packaging material when tested at Europhartech.</p> <p>Addition of a new IPC at the packaging step at Europhartech.</p> <p>Deletion of the odour test from the finished product specification.</p> <p>Minor change to the particle size test method for praziquantel.</p> <p>Addition of a manufacturer responsible for batch release and batch control.</p> <p>Addition of a manufacturer responsible for primary packaging.</p> <p>Addition of a manufacturer responsible for secondary packaging.</p>
10 October 2025	<p>Test method for heavy metals has been removed from the specification for pyrantel embonate.</p> <p>Change in the specification limit of methanol for pyrantel embonate.</p>
10 October 2025	<p>To add an alternative test method for the determination of residual solvents in pyrantel embonate.</p> <p>To add an alternative test method for the determination of residual solvents in febantel.</p> <p>Change in the assay and purity test methods of the finished product.</p> <p>To adjust the process parameter of drying temperature at one of the finished product manufacturing sites.</p> <p>Addition of a test for degradation products at the finished product specification at release and at shelf-life.</p> <p>To adjust the IPC for residual moisture at one of the finished product manufacturing site.</p> <p>Addition of a manufacturing site of the finished product.</p>
21 May 2024	<p>CEP for the manufacture of an active substance deleted.</p> <p>CEP for the manufacture of an active substance deleted.</p> <p>CEP for the manufacture of an active substance updated to a newer version.</p>
19 October 2021	<p>Introduction of a new pharmacovigilance system.</p>
05 November 2020	<p>Change of MAH from Bayer Animal Health GmbH, 51368</p>

	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