



## Post Authorisation Assessments

### Johnson's Wormer Plus 150/144/50 mg Tablets for Dogs & Puppies Vm 08007/4168

16 October 2025	Administrative changes: - Change in distributor details from Vetoquinol UK Limited to Johnson's Veterinary Products Ltd. Change in pack size of the finished product: - Change in the number of tablets in a pack outside the range of the currently approved pack size. Change in Legal Category from NFA-VPS to AVM-GSL. Alignment of the product information with version 9.0* of the QRD templates.
05 August 2025	Change in pack size (number of units e.g. tablets, ampoules, etc. in a pack) within the range of the currently approved pack size.
29 April 2025	Introduction of a new site of micronisation for the manufacturer of the active substance.
12 February 2025	Micronisation site for febantel has been declared. Particle size limits have been included in the specification for febantel.
05 February 2025	Change in the invented name of the Veterinary Medicinal Product from Drontal Plus Flavour Tablets for Dogs to Johnson's Wormer Plus 150/144/50mg Tablets for Dogs & Puppies.
21 January 2025	Change in the test procedure for the packaging material when tested at Europhartech. Down scaling of the batch size of the finished product at Europhartech. Addition of a new specification parameter to the specification of the packaging material when tested at Europhartech. Addition of a new IPC at the packaging step at Europhartech. Deletion of the odour test from the finished product specification. Deletion of the alternative packaging material for the finished product. Minor change to the particle size test method for praziquantel. Addition of a manufacturer responsible for batch release and batch control. Addition of a manufacturer responsible for primary packaging. Addition of a manufacturer responsible for secondary packaging.
20 June 2024	To add an alternative test method for residual solvents determination in pyrantel embonate. To add an alternative test method for residual solvents determination in febantel. Change in test procedure for the finished product. Minor change in the manufacturing process. Change to in-process tests or limits applied during the manufacture of the finished product.

	Addition of a manufacturing site of the finished product.
21 May 2024	CEP for the manufacture of an active substance deleted. CEP for the manufacture of an active substance deleted. CEP for the manufacture of an active substance updated to a newer version.
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.