Veterinary Medicines Directorate

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Post Authorisation Assessments

Drontal Wormer 96 mg/24 mg Spot-on Solution for Large Cats

Vm 08007/5013

23 September 2026	Changes to the summary of the PSMF not already covered elsewhere in this Annex.
04 August 2026	Addition of a new specification parameter with test method.
05 June 2026	Change in test procedure for a reagent used in the manufacturing process of an active substance.
13 February 2026	Change in address or contact details of a manufacturer of the active substance where no European Pharmacopoeia Certificate of Suitability is part of the approved dossier. Addition of a new specification parameter to the specification with its corresponding test method for an active substance. Addition of a new specification parameter to the specification with its corresponding test method for a reagent used in the manufacturing process of the active substance.
09 February 2026	Change to a test procedure for the finished product.
08 December 2025	Submission of an updated CEP for the manufacture of an active substance.
29 October 2025	Introduction of a second manufacturing and testing site to manufacture Emodepside active substance.
29 October 2025	Change in the (invented) name of the veterinary medicinal product from Dronspot to Drontal Wormer.
29 October 2025	Addition of AEs to 4.6 as a result of MAH signal management processes.
20 June 2025	Minor change to an approved test procedure for the finished product.
21 February 2025	Change in the batch size downscaling down up to 10-fold compared to the originally approved batch size. Change in the batch size up to 10-fold increase compared to the originally approved batch size.
21 February 2025	Change in test procedure for the immediate packaging of the finished product. Change in the specification parameters or limits of the immediate packaging of the finished product. Addition of a manufacturer responsible for batch control and quality testing of the finished product. Deletion of a non-significant specification parameter in the specification parameters or limits of the immediate packaging of the finished product. Deletion of a non-significant specification parameter in the specification parameters or limits of the immediate packaging of the finished product. Deletion of a non-significant specification parameter in the specification parameters or limits of the immediate packaging of

	the finished product. Addition of a manufacturer responsible for batch release of the finished product. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
21 February 2025	Change to in-process tests or limits applied during the manufacture of the finished product: - Other changes. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
14 September 2022	Renewal
02 February 2022	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.
02 April 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
02 September 2019	Tightening of specification limits of a reagent used in the manufacturing process of the active substance.
25 July 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
17 May 2019	MRP to add 10 member states
28 June 2018	To change the legal distribution category from POM-V to NFA-VPS
22 May 2018	Change in the name supplier of a starting material used in the manufacture of the active substance. Minor change in the manufacturing process of the active substance. Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material used in manufacturing process of active substance from an already approved manufacturer.