Veterinary Medicines Directorate

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Post Authorisation Assessments

Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs

Vm 08007/5053

26 January 2026	Submission of an updated Ph. Eur. CEP for an active substance.
10 October 2025	Test method for heavy metals has been removed from the specification for pyrantel embonate. Change in the specification limit of methanol for pyrantel embonate.
10 October 2025	Change in the composition of the immediate packaging for a solid pharmaceutical form for a finished product. 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. Introduction of a micronisation site for febantel. Deletion of the odour test from the finished product specification. 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.
10 October 2025	To add an alternative test method for the determination of residual solvents in pyrantel embonate. To add an alternative test method for the determination of residual solvents in febantel. Change in the assay and purity test methods of the finished product. To adjust the process parameter of drying temperature at one of the finished product manufacturing sites. Addition of a test for degradation products at the finished product specification at release and at shelf-life. To adjust the IPC for residual moisture at one of the finished product manufacturing site. Addition of a manufacturing site of the finished product.
29 April 2025	Introduction of a new site of micronisation for the manufacturer of the active substance.
21 December 2023	Deletion of a Ph. Eur. CEP for the manufacture of an active substance. Deletion of a Ph. Eur. CEP for the manufacture of an active substance. 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	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.
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.
24 July 2019	Change in the invented name of the veterinary medicinal product from Bob Martin Clear 3 in 1 Wormer XL 525/504/175 mg Tablets for Large Dogs to Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs. Addition of components (excipients) of the flavouring or colouring system of the finished product. Changes to the labelling and package leaflet.
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 MAH 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.
18 November 2015	Update of a manufacturing site address for secondary assembly only.
20 November 2014	Change in the invented name of the medicinal product, from ‘Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs’ to ‘Bob Martin Clear 3 in 1 Wormer XL 525/504/175 mg Tablets for Large Dogs’.
31 July 2013	Deletion of two non-significant parameters of an active substance used in the manufacturing process of the active substance.
17 January 2013	Change in Legal category from NFA-VPS to AVM-GSL.
04 July 2012	Addition of a distributor.
07 September 2011	Change in name of Veterinary Medicinal Product from: Drontal Plus XL Tablets to Bob Martin 3 in 1 Dewormer XL Tablets for Large Dogs.
18 April 2011	Update of Active Substance Master File (ASMF).
09 February 2011	Change of Distributor to Unidrug Distribution Group Ltd.
10 March 2010	Variation to remove the wording 'To be supplied only on a veterinary prescription' from the carton and package leaflet.
15 March 2007	Variation to update product literature and SPC in line with new regulations and change legal category from PML to NFA-VPS.
21 February 2007	Renewal.
16 December 2004	Harmonisation of SPC.
14 May 2004	Change in specification of finished product.

18 September 2003	Change in MAH address.