



## Post Authorisation Assessments

### Bob Martin Clear 3 in 1 Flavoured Wormer 150/144/50 mg Tablets for Dogs Vm 08007/4154

05 February 2025	<p>Change in the manufacturer of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier.</p> <p>Change in the specification parameters of an active substance: - Other changes.</p>
16 October 2024	<p>Change in the test procedure for the packaging material when tested at Europhartech.</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>Deletion of the alternative packaging material for the finished product.</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>
16 October 2024	<p>To add an alternative test method for residual solvents determination in pyrantel embonate.</p> <p>To add an alternative test method for residual solvents determination in febantel.</p> <p>Change in the assay and purity test methods of the finished product.</p> <p>To adjust the process parameter drying temperature at one of the manufacturing sites.</p> <p>To adjust the IPC for residual moisture at one of the manufacturing site.</p> <p>Addition of a manufacturing site of the finished product.</p>
28 June 2024	<p>Change in the specification limit of methanol for pyrantel embonate.</p> <p>Test method for heavy metals has been removed from the specification for pyrantel embonate.</p>

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.
03 June 2021	Changes to the labelling and/or package leaflet. Change of distributor details from Bob Martin (UK) Limited, 8 Wemberham Lane, Yatton, Somerset, BS49 4BS to Pets Choice Limited, Wemberham Lane, Yatton, North Somerset, BS49 4BS.
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 150/144/50 mg Tablets for Dogs to Bob Martin Clear 3 in 1 Flavoured Wormer 150/144/50 mg Tablets for 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 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.
18 November 2015	Update of a manufacturing site address for secondary assembly only.
07 November 2014	Change in the invented name of the medicinal product, from 'Bob Martin 3 in 1 Dewormer Tablets for Dogs' to 'Bob Martin Clear 3 in 1 Wormer 150/144/50 mg Tablets for Dogs'.
27 November 2013	Change of manufacturer for the finished product.
16 August 2013	Change of immediate packaging of the finished product.

31 July 2013	Deletion of 2 non-significant parameters of an active substance used in the manufacturing process of the active substance.
17 January 2013	Change of Legal category from NFA-VPS to AVM-GSL.
04 July 2012	Addition of Bob Martin UK Ltd as a distributor.
07 September 2011	Variation to change the name of the product from Drontal Plus Tablets, to Bob Martin 3 in 1 Dewormer Tablets for Dogs.
14 April 2011	Update of Active Substance Master File (ASMF).
08 March 2011	Change in distributor to Unidrug Distribution Group Ltd.
15 June 2010	Corrections/simple text/layout changes to the SPC and product literature.
10 November 2008	Renewal.
15 March 2007	Variation to bring the SPC/Labels in line with new regulations.
17 December 2004	Renewal.
18 September 2003	Change in name/address of MAH.
20 January 2003	Harmonisation of SPC.
07 November 2001	Change of manufacturer of active substance.
31 August 2001	Additional Pack size.
30 August 2001	Additional pack size.
30 May 2001	Addition of a manufacturer of the active substance.
07 March 2001	Change in container shape.
13 December 1999	Addition of safety warning regarding pets coming into the country.
04 November 1999	Renewal.
21 March 1997	Change in Manufacturer of the active substance.