



## Post Authorisation Assessments

### Bob Martin Clear Wormer 20/230 mg Tablets for Cats & Kittens Vm 08007/4156

•	09 October 2024	<p>Change in coating weight of oral dosage forms or change in weight of capsule shells for a solid oral pharmaceutical form.</p> <p>Change in test procedure for the immediate packaging of the finished product.</p> <p>Downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical form.</p> <p>Increase up to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical form.</p> <p>Addition of new specification parameters to the immediate packaging specification with the corresponding test method.</p> <p>Change of specifications of an active substance to fully comply with the Ph. Eur.</p> <p>Deletion of Ph. Eur. CEPs for an active substance.</p> <p>Minor changes to an approved test procedure for active substance.</p> <p>Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.</p> <p>Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.</p>
•	09 October 2024	<p>Deletion of one of the authorised immediate packaging forms of the finished product that does not delete a strength or pharmaceutical form.</p> <p>Addition of a manufacturer responsible for batch release including batch control or testing of the finished product.</p> <p>Addition of a primary packaging site of the finished product.</p> <p>Addition of a secondary packaging site of the finished product.</p>
•	09 October 2024	<p>Minor change in the manufacturing process of the finished product.</p> <p>Changes in the composition (excipients) of the finished product.</p> <p>Addition of a manufacturing site for part or all of the manufacturing process of the finished product.</p> <p>Addition of a manufacturing site for part or all of the manufacturing process of the finished product.</p>

•	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	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.
•	02 October 2018	Changes to the labelling.
•	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.
•	03 May 2018	Change in the SPC, Labelling and Package Leaflet for products intended to implement the outcome of a procedure concerning a PSUR.
•	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.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	29 July 2014	Change to the invented product name from 'Bob Martin 2 in 1 Dewormer Tablets for Cats and Kittens' to 'Bob Martin Clear Wormer Tablets for Cats and Kittens'.
•	19 September 2013	Change in shape and dimensions of the pharmaceutical form. Change of batch size. Change of in process tests/limits applied during the manufacture of 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.
•	12 August 2011	Renewal procedure – Copycat.
•	02 March 2011	To update the active substance master file (ASMF).
•	16 February 2011	To change the distributor.

•	18 March 2008	To change the legal category.
•	03 October 2007	Change in name to Bob Martin 2 in 1 Dewormer Tablets for cats and kittens.
•	08 August 2007	To change the distributor.