



## Post Authorisation Assessments

### Wormclear 230 mg/20 mg Ellipsoid Film-coated Tablets for Cats Vm 08007/4174

•	11 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 to active substance specification to comply with 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>
•	11 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>
•	11 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	<p>Introduction of a new pharmacovigilance system.</p>

•	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.
•	15 October 2019	Addition of Distributor: Beaphar UK Limited, Rook Tree Farm, Withersfield Road, Great Wratting, Suffolk, CB9 7HD.