



Post Authorisation Assessments

Drontal Cat Film-coated Tablets Vm 08007/4162

•	18 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>
•	18 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>
•	18 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.
•	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 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.
•	27 May 2016	Delete a distributor.
•	8 December 2015	Addition of a secondary packaging site.
•	16 August 2013	Change in immediate packaging of the finished product
•	31 July 2013	Changes in specification parameters/limits of an active substance
•	21 June 2013	Changes to labelling/package leaflet that are not connected to the SPC
•	20 December 2011	Changes to labelling/package leaflet that are not connected to the SPC
•	23 November 2011	Change of product name from 'Drontal Cat Tablets' to 'Drontal Cat Film-coated Tablets'
•	14 April 2011	Submission of an updated Active Substance Master File (ASMF)
•	09 February 2011	Change of distributor
•	19 November 2010	Batch control
•	03 March 2010	Change to in-process tests/limits applied during manufacture of the finished product
•	04 February 2010	Change of batch size of the finished product
•	08 January 2009	Renewal
•	07 March 2007	Changes to SPC and Product Literature to bring in line with new legislation
•	16 December 2004	Renewal
•	18 September 2003	Change of MAH name and address
•	20 January 2003	Harmonisation of SPC
•	07 August 2002	Submission of TSE Certificate
•	30 May 2001	Change of manufacturer of active substance

•	07 March 2001	Change in type of non-sterile containers
•	13 December 1999	Change of user safety warnings
•	13 October 1999	Renewal
•	14 March 1995	Change of safety warnings