



Post Authorisation Assessments

Drontal Cat XL Film-coated Tablets Vm 08007/4163

22 August 2025	<p>Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile active substance.</p> <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>
02 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 primary packaging site of the finished product.</p> <p>Addition of a secondary packaging site of the finished product.</p>
02 October 2024	<p>Minor change in the manufacturing process of the finished product.</p> <p>Change in the specification parameters and/or limits 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</p>

	manufacturing process of the finished product. Addition of a manufacturing site for part or all of the manufacturing process of the finished product.
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	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 Unidrug Distribution Group Limited as a distributor.
18 November 2015	Update of a manufacturing site address for secondary assembly only.
16 August 2013	Change in immediate packaging of the finished product
31 July 2013	Changes to specification parameters of an active substance
12 February 2013	Update and re-wording of text on packaging
20 December 2011	Changes to the labelling/package leaflet that are not connected to the SPC
14 April 2011	Submission of an updated Active Substance Master File (ASMF)
09 February 2011	Change of distributor
23 February 2010	Change to in-process tests/limits applied during manufacture of the finished product
05 February 2010	Change of batch size Change of tablet dimensions
21 July 2009	Renewal
07 March 2007	Changes to the SPC and Product Literature to bring in line with new legislation
07 July 2005	Increase in shelf life from 36 months to 48 months
16 June 2005	Batch control
26 November 2004	Harmonisation of SPC

04 October 2004

Change of specification of finished product