



Post Authorisation Assessments

Drontal Dog Tasty Bone 150/144/50 mg Tablets Vm 08007/3002

•	13 June 2024	Substantial changes in the updated version of the ASMF.
•	12 June 2024	<p>Change in test procedure for the immediate packaging of the finished product.</p> <p>Change in the limits of an active substance specification parameter.</p> <p>Addition of a new specification parameter to the immediate packaging specification with its corresponding test method.</p> <p>Changes to the production process or the storage of active substance -introduction of a new site of micronisation of the active substance.</p> <p>Deletion of a non-significant specification parameter in the specification parameters or limits of the finished product.</p> <p>Deletion of a non-significant specification parameter in the specification parameters or limits of the finished product.</p> <p>Deletion of a non-significant specification parameter in the specification parameters or limits of the finished product.</p> <p>Minor changes to an approved test procedure for an active substance.</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>
•	12 June 2024	<p>Addition of a new test procedure for an active substance.</p> <p>Addition of a new test procedure for an active substance.</p> <p>Addition of a new test procedure for an active substance.</p> <p>Minor change in the manufacturing process of the finished product.</p> <p>Change in the specification parameters and/or limits of an active substance.</p> <p>Addition of a manufacturing site for part or all of the manufacturing process of the finished product.</p>
•	18 May 2024	<p>Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance, for a starting material.</p> <p>Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance, for a starting</p>

		material.
•	14 December 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	14 July 2023	Changes to the quality part of the dossier: Deletion of - a Ph. Eur. CEP for an active substance, for a starting material
•	14 July 2023	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: – active substance.
•	22 April 2022	Updates to package leaflet regarding dosage instructions.
•	08 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.
•	26 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.
•	15 October 2019	Renewal – UK as CMS
•	26 October 2018	Change in the safety database of an existing pharmacovigilance system as described in the DDPS
•	01 August 2018	Submission of a new Ph. Eur. certificate of suitability for an active substance used in manufacturing process from a new manufacturer.
•	10 January 2018	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 July 2016	Submission of an updated certificate of suitability. Increase in the shelf life of the finished product from 2 years to 3 years.
•	30 June 2016	Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH.