



Post Authorisation Assessments

Drontal Dog Tasty Bone XL 525/504/175 mg Tablets Vm 08007/3003

•	13 June 2024	Substantial changes in the updated version of the ASMF.
•	06 June 2024	Deletion of - a Ph. Eur. CEP for an active substance. Deletion of - a Ph. Eur. CEP for an active substance.
•	21 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.
•	23 September 2022	Renewal.
•	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.
•	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.

