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Post Authorisation Assessments

Drontal Plus Flavour Bone Shaped Tablets

Vm 08007/4167

O5 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, NM12 7Ls. O9 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. 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. Submission of a new Ph. Eur. certificate of suitability for an active substance excipient from a new manufacturer. 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. O5 May 2017 Change in the address of the marketing authorisation holder from Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD. Change in the address of the marketing authorisation holder from Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD. Change in the address of the marketing authorisation holder from Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD. Change in the address of the marketing authorisation holder from Bayer plc, 400 South Oak Way, Green Park, Reading Berkshire, RG2 6AD. O5 May 2017 Change to SPC & Product literature to implement the outcome of a procedure following PSUR. Delete Unidrug Distribution Group Limited as a distributor. 18 November 2015 Update of a manufacturing site address for secondary assembly only. 18 November 2013 Change of product literature. 17 October 2013 Changes of specification of the active substance Change of name of product substance Change of shape of tablet from 'Drontal Plus Flavour Tablets' to 'Drontal Plus Flavo	•	19 October 2021	Introduction of a new pharmacovigilance system.
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	•	26 March 2010	Renewal

•	15 July 2008	Submission of an updated Part II of the Dossier
•	03 April 2007	Harmonisation of SPC
•	13 December 2006	Changes to the SPC and Product Literature to bring in line with new legislation
•	19 July 2006	Change of shelf life from 2 years to 2 and a half years
•	27 February 2006	Change of product name from 'Multi-Worm Tablets for Dogs' to 'Drontal Plus Flavour Tablets'
•	24 August 2005	Change of pack size from cartons containing 2, 20 & 100 tablets, to cartons containing 2, 8, 24 & 104 tablets
•	14 July 2005	Change of manufacturer of an active substance
•	06 June 2005	Renewal
•	14 January 2005	Change in flavouring system of product
•	26 November 2003	Change of MAH address
•	30 August 2001	Addition of a manufacturer of an active substance