



## Post Authorisation Assessments

### Drontal Plus Flavour Bone Shaped Tablets Vm 08007/4167

•	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.
•	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.
•	20 February 2017	Changes to SPC & Product literature to implement the outcome of a procedure following PSUR.
•	27 May 2016	Delete Unidrug Distribution Group Limited as a distributor.
•	18 November 2015	Update of a manufacturing site address for secondary assembly only.
•	25 June 2014	Minor change to product literature.
•	17 October 2013	Layout changes to the Product Literature
•	31 July 2013	Changes of specification of the active substance
•	24 June 2011	Change of name of product from 'Drontal Plus Flavour Tablets' to 'Drontal Plus Flavour Bone Shaped Tablets' Change in dimensions of packaging
•	15 June 2011	Change of shape of tablet from round shape to bone shape
•	09 February 2011	Change of distributor
•	18 August 2010	Submission of an updated Part II of the Dossier
•	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