Veterinary Medicines Directorate

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Post Authorisation Assessments

Droncit Tablets 50 mg

Vm 08007/4158

•	04 August 2022	Change in test procedure for the immediate packaging of the finished product. Change in batch size of the finished product. Change in the specification parameters or limits of the immediate packaging of the finished product: – addition of a new specification parameter to the specification with its corresponding test method. Addition of a new in-process test and limits applied during the manufacture of the finished product. Deletion of an immediate packaging component. Minor changes to an approved test procedure for the active substance. Minor changes to an approved test procedure for the active substance. Addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product. Additional primary packaging site for the finished product. Additional secondary packaging site for the finished product.
•	04 August 2022	Change in manufacturing process of the finished product at Vetoquinol S.A.,Lure. Change in pack size outside the range of the currently approved pack size for the manufacturer Vetoquinol S.A.,Lure. Change to the specification parameters of the finished product. Changes to the in-process testing applied during manufacture of the finished product at Vetoquinol S.A.,Lure. Addition of manufacturing site for the finished product.
•	22 June 2022	Addition of a secondary packaging site of a finished product.
•	24 May 2022	Deletion of Ph. Eur. certificates of suitability for an active substance.
•	18 May 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	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.
•	03 March 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved 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.
•	28 November 2017	Changes to the labelling and/or package leaflet.
•	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.
•	16 August 2013	Change of immediate packaging of the finished product
•	31 July 2013	Change in specification parameters of an active substance
•	18 April 2013	Changes to the label/package leaflet which are not connected to the SPC
•	18 January 2012	Update to part 2 of the dossier
•	16 February 2011	Change of distributor
•	22 September 2009	Addition of site of secondary assembly
•	10 November 2008	Renewal
•	07 March 2007	Changes to the SPC and Product Literature to bring in line with new legislation Change of legal category from GSL to AVM-GSL
•	16 December 2004	Renewal
•	18 September 2003	Change of address of MAH
•	20 January 2003	Harmonisation of SPC
•	06 August 2002	Submission of a TSE Certificate
•	31 January 2001	Change of type of non-sterile containers
•	27 January 2000	Change of safety warnings
•	29 December 1999	Renewal
•	20 August 1998	Change of finished product specification Change in formulation
•	22 June 1994	Review