Veterinary Medicines Directorate

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Post Authorisation Assessments

Equipalazone Original 1 g Oral Powder

Vm 10434/4005

•	13 March 2023	Addition of a new in-process test and limits applied during the manufacture of the finished product.
•	20 December 2022	Editorial changes to part 2 of the dossier.
•	22 November 2022	Editorial changes to part 2 of the dossier.
•	22 August 2022	Editorial changes to part 2B of the dossier.
•	18 July 2022	Deletion of a test procedure for the active substance. Deletion of a test procedure for the active substance.
•	08 February 2022	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place.
•	25 June 2021	Change in the address of the manufacturer of the finished product.
•	12 April 2021	Change in immediate packaging of the active substance.
•	14 February 2020	Change in the invented name of the veterinary medicinal product from Equipalazone 1 g Oral Powder to Equipalazone Original 1 g Oral Powder.
•	27 November 2019	Minor change in the manufacturing process of the finished product.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	18 June 2019	Deletion of packaging site.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	09 May 2018	Deletion of a manufacturing site for an active substance.
•	13 December 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	16 November 2017	Change in the SPC, labelling or package leaflet due to new data.
•	10 March 2017	Minor change in the manufacturing process of the finished product. Minor adjustments of the quantitative composition of the finished product with respect to excipients.
•	22 June 2016	Submission of an updated Ph. Eur. certificate of suitability
•	23 October 2015	Minor change to an approved test procedure for the finished product.
•	10 September 2015	Change in name of manufacturer of the finished product.
•	14 April 2015	Changes to the product labelling/package leaflet.
•	17 October 2014	Change to the address of the MAH.
•	13 June 2012	Submission of an updated Ph. Eur. Certificate of

		Suitability for an active substance from an already approved manufacturer.
•	10 October 2011	Change of name of manufacturer of the finished product.
•	02 August 2011	Addition of a manufacturer of the active substance.
•	06 April 2011	Change of formulation.
•	15 December 2010	Change of distributor.
•	15 January 2010	Change of specification of the finished product.
•	27 October 2009	Change in test procedure performed on the finished product.
•	28 August 2008	Addition of information regarding palatability to the SPC and Product Literature. Corrections to the SPC and Product Literature.
•	13 August 2008	Submission of an updated Active Substance Master File (ASMF).
•	24 July 2008	Change of specification of the finished product.
•	27 March 2008	Change in test procedure performed on the finished product.
•	11 June 2007	Harmonisation of the SPC.
•	28 February 2007	Change of immediate packaging composition.
•	02 January 2007	Change of SPC and Product Literature to bring in line with new legislation.
•	30 August 2006	Change of MAH.
•	05 April 2006	Submission of an updated Active Substance Master File (ASMF).
•	22 February 2006	Renewal.
•	31 January 2006	Submission of an updated Active Substance Master File (ASMF).
•	23 November 2005	Change of manufacturing process of the finished product. Change of batch size.
•	05 October 2005	Change of name/address of a manufacturer of the active substance.
•	07 April 2005	Change of specification of the finished product.
•	29 July 2003	Addition of safety warning regarding use in horses intended for human consumption.
•	21 March 2001	Addition of a manufacturer of the active substance.
•	28 March 2000	Renewal.
•	29 May 1997	Change of specification of the finished product. Change in shelf life.