Veterinary Medicines Directorate

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Post Authorisation Assessments

Equipalazone 1g Oral Paste

Vm 10434/4006

•	12 September 2023	Change in test method for the finished product to comply with Ph. Eur. Editorial changes to part 2 of the dossier.
•	20 February 2023	Deletion of a test procedure for an excipient.
•	11 January 2023	Change(s) in the composition (excipients) of a non-sterile finished product - replacement of a component or components of the flavouring system.
•	12 July 2022	Editorial changes to parts 2A and 2B of the dossier.
•	01 April 2022	Addition of a site where batch control/testing takes place.
•	15 August 2019	Tightening of in-process limits applied during the manufacture of the finished product.
•	18 June 2019	Addition of a manufacturer responsible for batch release including batch control/testing.
•	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.
•	22 June 2016	Submission of an updated Ph. Eur. certificate of suitability
•	14 April 2015	Changes to the product labelling/package leaflet.
•	17 October 2014	Change to the address of the MAH.
•	07 July 2014	Submission of an updated Ph. Eur. Certificate of Suitability for an already approved manufacturer of thee active substance.
•	23 May 2012	Addition of an active substance manufacturer
•	02 March 2011	Changes to the Product Literature artwork
•	15 December 2010	Change of distributor
•	05 May 2010	Minor change to manufacturing process of the finished product
•	20 January 2010	Change of description of product from ‘pale yellow’ to ‘off white’
•	28 August 2008	Update to withdrawal period on the SPC and Product Literature
•	11 June 2007	Harmonisation of the SPC
•	02 January 2007	Change of legal category from POM to POM-V Changes to the SPC and Product Literature to bring in line with new legislation
•	25 October 2006	Change of vanilla flavouring

•	28 September 2006	Batch control
•	21 September 2006	Change of product name from ‘Equipalazone Paste E-PP’ to ‘Equipalazone 1g Oral Paste’
•	30 August 2006	Change of MAH
•	05 April 2006	Submission of an updated Active Substance Master File (ASMF)
•	22 February 2006	Renewal
•	07 December 2001	Addition of a manufacturer of the active substance
•	10 February 2000	Renewal
•	20 July 1995	Change of safety warnings Change to formulation