Veterinary Medicines Directorate

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Post Authorisation Assessments

Prednisolone 5 mg Tablets

Vm 10434/4065

•	01 July 2022	Updated certificate of suitability from an already approved manufacturer for an active substance.
•	24 June 2022	Deletion of an active substance manufacturer.
•	22 June 2022	Deletion of a manufacturer of the finished product.
•	21 June 2022	Addition of a batch testing site for the finished product.
•	08 March 2021	Decrease in batch size range of the finished product.
•	17 September 2020	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	12 February 2019	Changes to an existing pharmacovigilance system as described in the DDPS.
•	11 October 2017	Changes to the labelling and/or package leaflet.
•	29 September 2016	Change in the address of the Marketing Authorisation Holder.
•	14 November 2014	Submission of a new Ph. Eur. Certificate of Suitability.
•	17 May 2012	Change in the immediate packaging of the finished product.
•	26 March 2012	Grouped variation to update the Certificate of Suitability for the active substance.
•	09 February 2010	Variation to change the Marketing Authorisation Holder.
•	20 January 2009	Renewal.
•	30 December 2008	Submission of a new or updated Certificate of Suitabilty.
•	21 August 2008	Change in the analytical method for assay of related subsances.
•	22 May 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
•	03 March 2008	Addition of an active substance manufacturer.