Veterinary Medicines Directorate

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Post Authorisation Assessments

Prednidale 5 mg Tablets
Vm 10434/4009

•	29 June 2022	Updated certificate of suitability from an already approved manufacturer for an active substance.
•	22 June 2022	Addition of a batch testing site for the finished product
•	22 June 2022	Deletion of a manufacturer of the finished product.
•	21 June 2022	Deletion of a manufacturing site for an active substance.
•	June 2022	Deletion of a manufacturer of 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.
•	17 January 2018	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.
•	26 January 2011	Variation to change the distributor.
•	30 December 2008	Variation to submit a new Certificate of Suitability for the active substance.
•	25 February 2008	Renewal.
•	19 October 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	21 September 2006	Change of Marketing Authorisation Holder.
•	11 July 2006	Change of distributor.
•	22 June 2006	Variation to change the analytical method for assay of related substances.
•	24 August 2005	Addition of an active substance manufacturer.
•	16 January 2004	Renewal.
•	27 June 2003	Addition of an active substance manufacturer.
•	22 May 2002	Extension of product shelf life.
•	24 August 1999	Addition of a manufacturer/assembler of dosage form.