Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

Prednidale 25 mg Tablets for Dogs

Vm 10434/4008

•	29 August 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Minor change in the manufacturing process. Change to in-process tests or limits applied during the manufacture of the finished product: - Addition or replacement of an in-process test as a result of a safety or quality issue.
•	05 July 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.
•	17 September 2020	Minor changes to an approved test procedure 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 for a new manufacturer.
•	21 February 2013	Extension of the finished product shelf life from 18 months to 48 months.
•	16 August 2012	Renewal procedure.
•	23 March 2012	Submission of a new updated Ph. Eur certificate of suitability.
•	26 January 2011	To change the distributor.
•	30 December 2008	Submission of a new updated Ph. Eur certificate of suitability for an active substance/ starting material/reagent or intermediate in the manufacturing process of the active substance.
•	27 June 2008	Change in the qualitative and/or quantitative composition of the immediate packaging.