Veterinary Medicines Directorate

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Post Authorisation Assessments

Prednizol 5 mg Tablets for Dogs and Cats

Vm 04409/3000

•	31 January 2024	Addition of immediate packaging of the finished product. Change in the number of units in a pack outside the range of the currently approved pack sizes.
•	27 June 2023	Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
•	17 March 2023	Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product. Change in the batch size of the finished product. Replacement of a batch control and testing site for the finished product. Deletion of a testing site. Replacement of a manufacturer responsible for batch release.
•	23 January 2023	Deletion of a manufacturing site of the finished product.
•	23 January 2023	Deletion of a microbiological testing site for the finished product.
•	07 December 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	19 May 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 June 2021	Deletion of a non-significant specification parameter of the finished product. Change in the specification parameters and/or limits of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	03 November 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	29 September 2020	Addition of a carton as secondary packaging. Changes to the labelling and/or package leaflet.
•	12 February 2020	RMS change from UK to NL