Veterinary Medicines Directorate

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Post Authorisation Assessments

Prednisolone Tablets B.P. (Vet) 5 mg

Vm 04409/4003

•	27 June 2023	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - As packaged for sale.
•	22 December 2022	Addition of a microbiological testing site.
•	07 December 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
•	19 August 2022	Change in batch size of the finished product. Replacement quality control testing site for the finished product. Additional batch release site for the finished product.
•	18 May 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	01 April 2021	Change in storage conditions of the finished product.
•	11 March 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Deletion of a non-significant specification parameter 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.
•	22 January 2020	Update of ingredients of ruminant origin.
•	14 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	24 December 2019	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Addition of a site where batch control/testing takes place. Deletion of manufacturing site for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	17 December 2019	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.
•	22 August 2018	Changes in the qualitative and quantitative composition of the immediate packaging of the finished product for solid pharmaceutical forms. Deletion of a manufacturing site, packaging site and testing.
•	11 June 2018	Addition of a site where batch control/testing takes place.
•	01 September 2011	Addition of a tester of final dosage form (from outside EU).
•	01 September 2011	Replacement of an importer of the final dosage form (from outside EU).
•	05 September 2008	Change in the test procedure for the finished product.
•	25 June 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to pOM-V.
•	17 June 2008	Shelf life extension.
•	17 June 2008	Addition of a manufacturer/assembler of the dosage form.
•	07 April 2008	Variation to change the bossing on tablets.
•	07 August 2007	Renewal.
•	19 October 2005	Addition of an active substance manufacturer.
•	22 August 2003	Renewal.
•	30 October 2002	Change to FPS.
•	03 February 1998	Change to the formulation of the finished product.