Veterinary Medicines Directorate

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Post Authorisation Assessments

Prednisolone 5 mg Tablets

Vm 10434/4065

01 December 2024	Change to comply with pharmacopoeia.
23 November 2024	Change of imprints, bossing or other markings of the finished product. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible.
11 August 2023	Change in pack size of the finished product: - Change in the number of units (e.g., tablets, ampoules, etc.) in a pack outside the range of the currently approved pack sizes.
26 May 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.
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.