Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Prednisolone 5 mg Tablets

Vm 10434/4065

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| 01 December 2024 | Change to comply with pharmacopoeia. |
| 23 November 2024 | Change of imprints, bossing or other markings of the finished product.<br>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.<br>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. |