



Post Authorisation Assessments

Prednidale 5 mg Tablets

Vm 10434/4009

•	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.
•	29 June 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
•	22 June 2022	Deletion of a manufacturer of the finished product.
•	21 June 2022	Deletion of a manufacturing site for an active substance.
•	June 2022	Deletion of a manufacturer of 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.
•	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.
•	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.
•	26 January 2011	Variation to change the distributor.
•	30 December 2008	Variation to submit a new Certificate of Suitability for the active substance.
•	25 February 2008	Renewal.
•	19 October 2006	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	21 September 2006	Change of Marketing Authorisation Holder.
•	11 July 2006	Change of distributor.

•	22 June 2006	Variation to change the analytical method for assay of related substances.
•	24 August 2005	Addition of an active substance manufacturer.
•	16 January 2004	Renewal.
•	27 June 2003	Addition of an active substance manufacturer.
•	22 May 2002	Extension of product shelf life.
•	24 August 1999	Addition of a manufacturer/assembler of dosage form.