



## Post Authorisation Assessments

### Prednidale 5 mg Tablets Vm 50406/5030

15 August 2025	Change to the quality testing site for the finished product.
08 April 2025	Change in legal entity of MA holder from Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom to Dechra Regulatory B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands.
12 December 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible
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.
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.