



Post Authorisation Assessments

Prednidale 25 mg Tablets for Dogs

Vm 50406/5029

24 November 2025	Minor changes to an approved test procedure for an excipient. Tightening of specification limits of an excipient.
17 October 2025	Change to comply with a national pharmacopoeia. Change to comply with a national pharmacopoeia. Change to comply with a national pharmacopoeia Change to comply with a national pharmacopoeia. Addition of a manufacturer responsible for quality control and batch release.
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
11 December 2024	Approval of mock ups.
01 December 2024	Change to comply with pharmacopoeia.
18 June 2024	Change to the SPC and PL to implement the finding during a PSUR procedure. Sections 4.5 Special precautions for use, 4.6 Adverse reactions (frequency and seriousness) and 4.8 Interaction with other medicinal products and other forms of interaction of the SPC. And section 6. Adverse reactions and 12. Special warning(s) from package leaflet.
29 August 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.
05 July 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.
17 September 2020	Minor changes to an approved test procedure 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 for a new manufacturer.

21 February 2013	Extension of the finished product shelf life from 18 months to 48 months.
16 August 2012	Renewal procedure.
23 March 2012	Submission of a new updated Ph. Eur certificate of suitability.
26 January 2011	To change the distributor.
30 December 2008	Submission of a new updated Ph. Eur certificate of suitability for an active substance/ starting material/reagent or intermediate in the manufacturing process of the active substance.
27 June 2008	Change in the qualitative and/or quantitative composition of the immediate packaging.