Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Zycortal 25 mg/ml Prolonged-release Suspension for Injection for Dogs

Vm 50406/5053

23 March 2026	Deletion of a non-significant specification parameter in the specification parameters of the immediate packaging of the finished product.
10 December 2025	Deletion of a batch release site for the finished product. Deletion of a Quality control testing site for the finished product. Replacement of a quality testing site.
06 October 2025	Change of legal entity of the Marketing Authorisation Holder in GB only, 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.
28 August 2025	Alignment of the product information with version 3.0* of the QRD templates.
21 July 2025	Change in the name of a manufacturer (Quality Control) of the finished product.
12 February 2025	Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate). Changes to the quality part of the dossier. Minor changes:– to an approved test procedure for active substance. Replacement or addition of a supplier of packaging components. Replacement or addition of a supplier of packaging components.
12 February 2025	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacture.
09 October 2023	Change in the procedure for an already approved method of analysis of the active substance.
09 October 2023	Change in the procedure for an already approved method of analysis of the finished product.
17 May 2023	Change in test procedure for the container-closure integrity of the finished product.
30 November 2022	Editorial changes to part 2 of the dossier.
19 March 2021	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Deletion of a non-significant specification parameter of the finished product.