Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetoryl 5 mg Hard Capsules for Dogs

Vm 10434/5009

•	27 February 2024	Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
•	25 January 2024	Change in the address or contact details of a manufacturer or supplier of the starting material, used in the manufacture of the active substance where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. Change to comply with Ph. Eur. for the starting material used in the manufacture of the active substance. Changes to a test procedure for a reagent used in the manufacturing process of the active substance: – for a reagent, which does not have a significant effect on the overall quality of the active substance. Changes to the quality part of the dossier: Deletion of a test procedure for a reagent used in the manufacture of the active substance. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter of an active substance. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Minor changes: – to an approved test procedure for the active substance.
•	28 November 2023	One-off alignment of the product information with version 1 of the National QRD template.
•	25 August 2023	Deletion of a non-significant specification parameter in the finished product specification. Deletion of a non-significant specification parameter in the finished product specification. Deletion of a non-significant specification parameter in the finished product specification.
•	25 August 2023	Minor changes:– to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device.
•	18 August 2023	Change to an approved stability protocol of the finished product.
•	08 March 2023	Deletion of a non-significant specification parameter of the finished product.
•	08 February 2023	Deletion of a non-significant in-process test during the manufacture of the finished product.

•	23 January 2023	Editorial changes to part 2 of the dossier.
•	07 September 2022	Deletion of a non-significant in-process test during the manufacture of the finished product.
•	28 July 2022	Editorial changes to Part II B of the dossier for the 10 mg hard capsules. Editorial changes to Part II C of the dossier for the 5 mg and 60 mg hard capsules. Editorial changes to Part II F of the dossier for the 30 mg, 60 mg and 120 mg hard capsules.
•	29 March 2022	Deletion of a non-significant in-process test applied during the manufacture of the finished product.
•	23 September 2021	Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	23 June 2021	Change in immediate packaging of the active substance.