

Post Authorisation Assessments

Vetoryl 10 mg Hard Capsules for Dogs Vm 10434/3001

•	28 April 2024	Deletion of a non-significant specification parameter in
	•	the specification parameters of the finished product.
•	19 March 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 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.
•	27 February 2024	Change in qualitative composition of the immediate packaging for a solid pharmaceutical form for a finished product.
•	28 November 2023	One-off alignment of the product information with version 9.0* of the QRD template.
•	16 November 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.
•	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.
•	16 November 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product.
•	23 September 2021	Addition of a primary packaging site of the finished product.

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06 October 2010 To change the Marketing Authorisation Holder.	•		
	•	06 October 2010	To change the Marketing Authorisation Holder.

•	17 September 2010	Change in immediate packaging of the finished product.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
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•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	17 September 2010	Submission of new or updated Ph. Eur Certificates of Suitability.
•	23 October 2008	Change shelf life of finished product from 2 years to 3 years.
•	03 October 2008	Change active substance batch size