Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetmedin 10 mg Chewable Tablets for Dogs

Vm 08327/5021

•	05 September 2023	Introduction of a new site of micronisation for the manufacturer of the active substance.
•	18 August 2023	Updated Ph. Eur. CEP from an already approved manufacturer for an active substance.
•	13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	24 December 2021	Introduction of a new site of manufacture. Change in the address of the site of micronisation. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	20 January 2021	Change in the name of a manufacturer of the finished product.
•	23 September 2020	Addition to a test procedure for an excipient.
•	26 August 2020	Change in shape or dimensions of the container or closure (immediate packaging)
•	15 October 2019	Editorial changes.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	18 July 2019	Deletion of manufacturing site for a finished product.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 December 2018	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	09 November 2018	Change of MAH, from Boehringer Ingelheim Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS to Boehringer Ingelheim Animal Health UK Ltd, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS.
•	07 September 2017	Submission of an updated Ph. Eur. certificate of suitability.
•	05 September 2017	Addition of a new therapeutic indication.
•	02 August 2016	Change in the invented name of the veterinary medicinal product in Finland, Iceland, Lithuania, Norway and Sweden.
•	26 November 2015	Renewal – UK as CMS
•	04 February 2015	Changes to sections 4.2, 4.4, 4.5 and 5.1 of the SPC and corresponding product literature.
•	21 October 2014	To add an additional manufacturer of the finished product. To add a site responsible for EU – batch release for the

		product manufactured at the additional manufacturer. To add a new site for EU – batch testing.
•	15 September 2014	Addition of an alternative test procedure for the finished product.
•	11 September 2014	Submission of an updated Ph. Eur. Certificate of Suitability for active substance, changing the re-test period.