Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetmedin 5 mg Chewable Tablets for Dogs

Vm 08327/3018

•	15 March 2024	One-off alignment of the product information with version 9.0* of the QRD templates.
•	15 December 2023	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	01 December 2023	Addition of new micronisation site.
•	01 December 2023	Update of active substance CEP to most current version.
•	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.
•	19 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.
•	31 October 2017	Tightening of specification limits of the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product. Changes to a test procedure for the finished product.
•	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.
•	24 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 October 2014	To extend the shelf-life of the finished product, as packaged for sale, from 2 years to 3 years.
•	11 September 2014	Submission of an updated Ph. Eur. Certificate of Suitability for active substance, changing the re-test period.
•	04 July 2014	Change to the invented name of the product in the UK, Ireland and France, from ‘Pimobendan Vetmedica’ to ‘Vetmedin’ and from ‘Vetmedin’ to ‘Vemedin vet.’ in Italy.
•	06 December 2013	Change in the invented name of the product in IT, FI, IS, NO and SE only.
•	01 August 2013	Change in the invented name of the product in Belgium, France, Luxembourg and The Netherlands. Change to an existing pharmacovigilance system as described in the DDPS.
•	04 December 2012	Harmonisation of the SPC and product literature following a repeat use European procedure.