Veterinary Medicines Directorate

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Post Authorisation Assessments

Vetmedin 0.75 mg/ml Solution for Injection for Dogs

Vm 08327/3027

•	14 November 2023	Submission of an updated CEP approved.
•	14 November 2023	Additional site of micronisation for the active substance.
•	24 August 2023	Introduction of a new site of micronisation for the manufacturer of the active substance.(GB)
•	15 August 2023	Updated Ph. Eur. CEP from an already approved manufacturer for an active substance. (GB)
•	13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
•	10 March 2023	Deletion of a manufacturer of the finished product.
•	09 February 2023	Deletion of a manufacturer of the finished product.
•	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.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	16 September 2019	Renewal – UK as CMS
•	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.
•	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.
•	16 January 2017	Change in the RMS from the UK to AT.
•	07 September 2017	Change in the invented name of the veterinary medicinal product from Pimobendan Vetmedica to Vetmedin vet 0.75mg/ml Solution for Injection for Dogs in DK only.
•	23 August 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	13 June 2017	Addition of a site where batch control/testing takes place. Addition of a site where batch control/testing takes place. Addition of a manufacturer responsible for batch release including batch control/testing. Deletion of a non-significant in-process test applied during the manufacture of the finished product Deletion of a non-significant in-process test applied

		during the manufacture of the finished product Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product. Minor change in the manufacturing process of an immediate release solid oral dosage form. Addition of a manufacturing site of the finished product. Change to in-process tests applied during the manufacture of the finished product. Change to in-process tests applied during the manufacture of the finished product. Change to in-process tests applied during the manufacture of the finished product.
•	08 September 2016	Approval of joint labelled mock ups.
•	27 June 2016	Change in the (invented) name of the medicinal product in DE and UK to Vetmedin 0.75 mg/ml Solution for Injection for Dogs.