



Post Authorisation Assessments

Vetmedin Chew 5 mg Chewable Tablets for Dogs

Vm 08327/3030

•	14 November 2023	Update of CEP for manufacture of active substance updated to newest version.
•	14 November 2023	Addition of new site of micronisation.
•	23 August 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.
•	14 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.
•	09 February 2021	Minor changes to an approved test procedure of the finished product.
•	02 March 2020	Renewal – UK as CMS
•	13 February 2020	Addition of a site where batch testing takes place.
•	24 September 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
•	30 May 2019	Addition of a secondary packaging site of the finished product.
•	26 April 2019	Introduction of a new site of manufacture.
•	26 April 2019	Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product.
•	06 March 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 February 2019	Change in the invented name of the veterinary medicinal product from Vetmedin to Vetmedin vet in HR only.
•	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.
•	01 August 2018	Reduction of the shelf life of the finished product as packaged for sale from 30 months to 2 years. Deletion of a non-significant specification parameter of

		the finished product.
•	11 July 2018	Addition of a secondary packaging site of the finished product.
•	29 January 2018	Minor change in the manufacturing process of the finished product. Addition of a manufacturing site of the finished product.
•	16 October 2017	Change in the specification limits of the finished product.
•	07 September 2017	Submission of an updated Ph. Eur. certificate of suitability.
•	05 September 2017	Addition of a new therapeutic indication.
•	16 August 2016	Introduction of a new pharmacovigilance system which has been assessed by the relevant national competent authority/EMA for another product of the same MAH.
•	10 August 2016	Change in the (invented) name of the medicinal product in the Czech Republic, Denmark, Finland, Iceland, Lithuania, Norway, Poland and Sweden only.
•	17 December 2015	Approval of mock-ups Change of Distributor
•	10 November 2015	Change in the invented name of the medicinal product from Pimovita to Vetmedin Chew
•	28 October 2015	A change in Marketing Authorisation Holder.