Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS Telephone +44 (0)1932 336911

Post Authorisation Assessments

Vetmedin Chew 10 mg Chewable Tablets for Dogs Vm 08327/4318

•	16 November 2023	Change in test procedure for the finished product to
	1011010111001 2020	comply with Ph. Eur. (GB)
		Minor changes to an approved test procedure for the
		finished product. (GB)
•	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
	04.5	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
_	00 Fobruary 2024	approved manufacturer. Minor changes to an approved test procedure of the
•	09 February 2021	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
	4 4 4 4 4 4 4 4	Avenue, Bracknell, Berkshire, RG12 8YS.
•	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.