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Post Authorisation Assessments

Vetmedin Chew 2.5 mg Chewable Tablets for Dogs Vm 08327/3029

•	25 March 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
_	14 November 2023	
•	14 November 2023	Update of CEP for manufacture of active substance
	44 N	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
	o i August 2010	Reduction of the shell life of the liftished 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.
•	08 February 2018	Change in shape or dimensions of the container or
		closure (immediate packaging).
•	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.
•	03 May 2016	Change in Distributor details from Zylavet to Boehringer
		Ingelheim Ltd.
•	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.
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