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Post Authorisation Assessments

VetUK Cat Wormer 16 mg/40 mg Film-coated Tablets for Cats Vm 17902/4069

	25 March 2024	Undate to a Dh. Eur. CED for an already authorized
•	25 March 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.
		Update to a Ph. Eur. CEP for an already authorised
		manufacturer of the active substance.
_	30 December 2022	Change in synthesis or recovery of a non-
•	30 December 2022	
		pharmacopoeial excipient or a novel excipient.
		Change in the specification parameters and/or limits of
_	00 February 2022	an excipient.
•	08 February 2022	Minor change in the manufacturing process of the finished product.
•	11 January 2022	Minor changes to an approved test procedure of the
		finished product.
		Deletion of a non-significant specification parameter of
		the immediate packaging of the finished product.
•	30 September 2021	Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
		Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
		Submission of a new Ph. Eur. certificate of suitability for
		an active substance from an already approved
		manufacturer.
•	23 September 2021	Change(s) in the SPC, to section 4.6 to implement the
		outcome of a PSUR procedure by adding hypersensitivity
	_	reactions
•	07 September 2020	Submission of a new Ph. Eur. certificate of suitability for
		an active substance from an already approved
		manufacturer.
		Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
		Submission of a new Ph. Eur. certificate of suitability for
		an active substance from a new manufacturer.
		Introduction of a re-test period of the active substance.
•	26 March 2020	Change in the contact details of the QPPV of an existing
		pharmacovigilance system as described in the DDPS.
•	28 June 2019	Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
		Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already

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		approved manufacturer.
•	28 June 2019	Renewal – UK as RMS.
•	18 March 2019	Change in RMS from UK to FR.
•	31 May 2018	Change of specification(s) of a former non
		Pharmacopoeial active substance to comply with the Ph.
		Eur. or with a national pharmacopoeia of a Member
		State.
•	18 April 2018	Change in the SPC, labelling or package leaflet following
		assessment of the same change for the reference
	00.1	product.
•	09 January 2018	Deletion of a manufacturing site for an active substance.
•	22 June 2017	Deletion of a manufacturing site for an active substance.
•	29 March 2017	Submission of a new or updated Ph. Eur. Certificate of
		Suitability.
		Addition of a manufacturer of the active substance.
•	17 May 2016	Increase in the shelf-life of the finished product as
		packaged for sale, from 2 years to 3 years.
•	31 March 2016	Variation to add a new indication for <i>Echinococcus</i>
		mulitilocularis infections.
•	14 January 2016	Submission of a new or updated Ph. Eur. certificate of
_	06 Fobruary 2015	Suitability.
•	06 February 2015	Change in the invented name of the medicinal product in France only, from 'Milbekan' to Milprazikan'.
•	02 October 2014	Change in the invented name of the medicinal product
		from 'Milprotect', to 'VetUK Cat Wormer' in the UK, and
		to 'Milbekan' in France.
•	18 September 2014	Variation to update the ASMF for an active substance.