

Post Authorisation Assessments

Milgusto Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg Vm 01656/5087

•	19 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.
•	06 March 2024	Submission of a new Ph. Eur. certificate of suitability for
		a manufacturer of the active substance.
•	02 March 2023	Unlimited renewal.
•	08 March 2022	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 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.
		Submission of a new Ph. Eur. certificate of suitability for
		an active substance.
•	28 January 2022	Addition of a primary packaging site of the finished
		product.
		Addition of a secondary packaging site of the finished
		product.
		Addition of a manufacturing site of the finished product.
•	13 August 2021	Updates to the product literature following a Periodic
		Safety Update Report.
•	11 November 2019	Change in the invented name of the veterinary medicinal
		product from Aderexa 16 mg/40 mg Film-coated Tablets
		for Cats Weighing at Least 2 kg to Milgusto Chewable 16
		mg/40 mg Film-coated Tablets for Cats Weighing at
		Least 2 kg.
•	10 September 2019	Change to an in-process test applied during the
		manufacture of the finished product.
		Changes of components (excipients) of the flavouring or
		colouring system of the finished product.
		Changes in components (excipients) of the flavouring or colouring system of the finished product.
		Changes to a test procedure for the finished product.
		Changes to a test procedure for the finished product.
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Replacement of an excipient with a comparable
excipient.