Veterinary Medicines Directorate

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Post Authorisation Assessments

Milbeworm 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens

Vm 17902/4080

•	19 March 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	15 November 2022	Change in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier) or a novel excipient. Change in the specification parameters and/or limits of an excipient
•	18 February 2022	Minor change in the manufacturing process of the finished product.
•	10 December 2021	Changes in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning a periodic safety update report.
•	18 November 2021	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.
•	13 August 2021	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 an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	23 July 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.
•	01 June 2020	Renewal - National.
•	25 February 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	19 February 2020	Change in distributor details from ANIMED DIRECT Ltd,

		12b Progress Way, Mid Suffolk Business Park, Eye, Suffolk, IP23 7HU to CVS (UK) Limited, CVS House, Owen Road, Diss, Norfolk, IP22 4ER.
•	22 May 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 approved manufacturer.
•	18 October 2018	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
•	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.
•	18 January 2017	Submission of a new certificate of suitability.
•	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 *Echinococcus mulitilocularis* infections.
•	26 February 2015	Changes to the manufacturing process for the active substance.