Veterinary Medicines Directorate

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Post Authorisation Assessments

Milquantel 12.5 mg/125 mg Tablets for Dogs Weighing at Least 5 kg

Vm 01656/3089

•	April 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	18 April 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of an active substance.
•	26 January 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	22 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.
•	16 March 2022	Changes in the SPC, Labelling / Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	10 December 2021	Addition of a manufacturer responsible for batch release of the finished product.
•	13 August 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	26 January 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.
•	17 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	04 June 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	23 December 2019	Renewal – UK as CMS.
•	19 June 2019	Addition of a manufacturing site of the finished product.
•	18 April 2019	Addition of a site where batch control/testing takes place. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product.
•	18 April 2019	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.
•	14 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.

•	26 September 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	01 August 2018	To harmonise and finalise SPCs and QRDs after a repeat-use procedure.
•	18 May 2018	Change in RMS from UK to NL.
•	25 October 2017	Deletion of a manufacturing site of the active substance.
•	19 October 2017	Increase in the shelf-life of the finished product as packaged for sale from 2 years to 3 years.
•	25 July 2017	Change in distributor details. Deletion of Intervet UK Ltd and addition of Alloga UK Limited, Centaur Services Limited & National Veterinary Services Limited.
•	12 June 2017	Repeat Use application to add 2 new member states
•	08 December 2016	Addition of a secondary packaging site of the finished product.
•	24 August 2016	Change in test procedure for the active substance.
•	25 August 2016	Addition of a manufacturer of the active substance.
•	09 June 2016	Submission of a new Certificate of Suitability.
•	03 September 2015	Introduction of a new pharmacovigilance system.
•	10 July 2015	Change of MAH. Addition of distributors and a local UK representative. Approval of mock-ups.