Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 01656/3093

•	June 2024	Minor change in the manufacturing process of the finished product.
•	22 June 2024	Alignment with version 9.0 of the QRD template in accordance with Regulation (EU) 2019/6.
•	04 May 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.
•	13 January 2021	Renewal – UK as CMS.
•	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.
•	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.
•	18 May 2018	Change of RMS from UK to NL.
•	10 January 2018	MRP UK as RMS
•	16 February 2017	Deletion of a manufacturing site of the active substances.
•	16 February 2017	Change in pack size of the finished product.
•	10 November 2016	Addition of secondary packaging site of the finished product.
•	19 August 2016	Addition of a manufacturing site for the active substance.
•	09 June 2016	Submission of a new Ph. Eur. certificate of suitability for Praziquantel.