Veterinary Medicines Directorate

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Post Authorisation Assessments

Milprazin 4 mg/10 mg Film-coated Tablets for Small Cats and Kittens Weighing at Least 0.5 kg

Vm 01656/3096

•	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.
•	13 January 2023	Minor changes to an approved test procedure for the active substance.
•	08 August 2022	Minor changes to an approved test procedure for the 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.
•	17 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.
•	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.
•	06 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.
•	30 April 2020	Increase in the shelf-life of the finished product after first opening, from 3 months to 6 months.
•	05 December 2019	Replacement of a manufacturing site of the finished product.
•	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.
•	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 in RMS from UK to NL.
•	10 January 2018	MRP UK as RMS
•	15 February 2017	Deletion of a manufacturing site of the active ingredients.
•	15 February 2017	Deletion of a 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.
•	08 June 2016	Submission of a new Ph. Eur. certificate of suitability for Praziquantel.