Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 01656/3076

•	May 2024	Amendments to the product information to align with version 9.0 of the QRD template.
•	14 May 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
•	11 May 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.
•	04 May 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
•	06 April 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.
•	04 February 2022	Changes to the labelling and/or package leaflet.
•	16 December 2021	Addition of a manufacturer responsible for batch release of the finished product.
•	27 October 2021	Updates to the Summary of Product Characteristics and product literature in line with required amendments.
•	01 September 2021	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
•	02 February 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.
•	21 December 2020	Changes to the labelling and/or package leaflet
•	16 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 August 2020	Changes to the labelling and/or package leaflet.
•	01 July 2020	Submission of a new Ph. Eur. certificate of suitability from a new manufacturer.

•	19 March 2020	Renewal – UK as CMS
•	27 June 2019	Addition of a manufacturing site of the finished product.
•	25 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.
•	25 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
•	06 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	05 December 2018	Change of specification of a former non Pharmacopoeial active substance to comply with the Ph. Eur.
•	31 May 2018	To harmonise and finalise SPCs and QRDs after a repeat-use procedure.
•	27 April 2018	Change in RMS from UK to IE.
•	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.
•	12 June 2017	Repeat Use application to add 5 new member states
•	21 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 site of manufacture for the active substance.
•	09 June 2016	Submission of a new Certificate of Suitability.