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 01656/5076

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| • | 27 December 2023 | Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. |
| • | 06 April 2022 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>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.<br>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.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>Submission of an updated Ph. Eur. certificate of |

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| | | suitability for an active substance from an already approved manufacturer. |
| • | 25 April 2019 | Addition of a site where batch control/testing takes place<br>Addition of a secondary packaging site of the finished product<br>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. |