

Post Authorisation Assessments

Milprazon Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg Vm 01656/3080

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| • | May 2024 | Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. |
| • | 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. |
| • | 06 March 2024 | Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance. |
| • | 06 July 2023 | Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability. Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability. |
| • | 20 February 2023 | Unlimited renewal |
| • | 08 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. Submission of a new Ph. Eur. certificate of suitability for an active substance. Submission of a new Ph. Eur. certificate of suitability for an active substance. |
| • | 04 February 2022 | Changes to the labelling and/or package leaflet. |
| • | 25 January 2022 | Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product. Addition of a manufacturing site of the finished product. |
| • | 22 December 2021 | Addition of a manufacturer responsible for batch release including batch control/testing. |
| • | 20 October 2021 | Change(s) in the SPC, Labelling or Package Leaflet intended to implement the outcome of a procedure concerning a PSUR. |
| • | 08 September 2020 | Change in the invented name of the veterinary medicinal product in EE, HU, IE and PL. |
| • | 29 October 2019 | Change in the invented name of the veterinary medicinal |

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| | | product from Amcofen 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg to Milprazon Chewable 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg. |
| • | 10 September 2019 | <p>Change to an in-process test applied during the manufacture of the finished product.</p> <p>Changes of components (excipients) of the flavouring or colouring system of the finished product.</p> <p>Changes in components (excipients) of the flavouring or colouring system of the finished product.</p> <p>Changes to a test procedure for the finished product.</p> <p>Changes to a test procedure for the finished product.</p> <p>Replacement of an excipient with a comparable excipient.</p> |