Veterinary Medicines Directorate

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# Post Authorisation Assessments

## Pramilon 16 mg/40 mg Film-coated Tablets for Cats

Vm 17902/4067

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| • | 09 April 2024 | Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance.<br>Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (GB) |
| • | 30 December 2022 | Change in synthesis or recovery of a non-pharmacopoeial excipient or a novel excipient.<br>Change in the specification parameters and/or limits of an excipient. |
| • | 08 February 2022 | Minor change in the manufacturing process of the finished product. |
| • | 11 January 2022 | Minor changes to an approved test procedure of the finished product.<br>Deletion of a non-significant specification parameter of the immediate packaging of the finished product. |
| • | 30 September 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.<br>Submission of a new Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 23 September 2021 | Change(s) in the SPC, to section 4.6 to implement the outcome of a PSUR procedure by adding hypersensitivity reactions. |
| • | 11 September 2020 | 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 a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.<br>Introduction of a re-test period of the active substance. |
| • | 27 March 2020 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 28 June 2019 | Renewal |
| • | 28 June 2019 | 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. |
| • | 08 March 2019 | Change in RMS from UK to FR. |
| • | 31 May 2018 | Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. |
| • | 18 April 2018 | Change in the SPC, labelling or package leaflet following assessment of the same change for the reference product. |
| • | 09 January 2018 | Deletion of a manufacturing site for an active substance. |
| • | 22 June 2017 | Deletion of a manufacturing site for an active substance. |
| • | 29 March 2017 | Submission of a new or updated Ph. Eur. Certificate of Suitability.<br>Addition of a manufacturer of the active substance. |
| • | 17 May 2016 | Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years. |
| • | 31 March 2016 | Variation to add a new indication for *Echinococcus mulitilocularis* infections. |
| • | 14 January 2016 | Submission of a new or updated Ph. Eur. certificate of suitability. |
| • | 02 October 2014 | Change in the invented name of the medicinal product, from 'Milprazin' to 'Pramilon' in the UK, 'Milbetel' in France, and 'No Worm Pro' in the Netherlands. |
| • | 18 September 2014 | To update the ASMF for the active substance. |