Veterinary Medicines Directorate

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Post Authorisation Assessments

Pramilon 12.5 mg/125 mg Film-coated Tablets for Dogs

•	11 January 2022	Minor changes to an approved test procedure of the finished product. 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. 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 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. 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 from a new manufacturer. 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	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 February 2019	Change in RMS from UK to FR.
•	31 January 2019	Renewal – UK as RMS
•	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.
•	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. 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.
•	14 January 2016	Submission of a new or updated Ph. Eur. certificate of suitability.
•	02 July 2015	Changes to the therapeutic indication.
•	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.