Veterinary Medicines Directorate

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Post Authorisation Assessments

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

Vm 05653/4182

•	01 March 2024	Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB) Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB)
•	30 December 2022	Change in synthesis or recovery of a non-pharmacopoeial excipient or a novel excipient. 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. 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.
•	04 September 2020	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new 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. Introduction of a re-test period of the active substance.
•	26 March 2020	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	04 March 2020	Repeat Use application to add 6 new member states
•	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.
•	11 April 2019	Renewal - UK as RMS
•	15 November 2018	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.
•	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. 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	Change to the therapeutic indication.
•	26 September 2014	Change to the product name in Italy only, from Milpro to Milpro Vet.
•	18 September 2014	Variation to update the ASMF for the active substance.