



Post Authorisation Assessments

Milpro 16 mg/40 mg Film-coated Tablets for Cats

•	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.
•	13 June 2019	Renewal- UK as RMS
•	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.
•	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.
•	31 March 2016	Variation to add a new indication for <i>Echinococcus multilocularis</i> infections.
•	14 January 2016	Submission of a new or updated Ph. Eur. certificate of suitability.
•	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.