Veterinary Medicines Directorate

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Post Authorisation Assessments

Milbactor 16 mg/40 mg Film-coated Tablets for Cats Weighing at Least 2 kg

Vm 01656/4083

•	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. (NI)
•	04 May 2024	Submission of a new Ph. Eur. certificate of suitability for a manufacturer of the active substance.
•	23 January 2024	Update to a Ph. Eur. CEP for an already authorised manufacturer of the active substance. (NI)
•	23 January 2024	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance. (GB)
•	13 January 2023	Minor changes to an approved test procedure for an in-process test for the finished product.
•	21 October 2022	Minor changes to an approved test procedure for an in-process test for the finished product.
•	06 April 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.
•	16 December 2021	Addition of a manufacturer responsible for batch release of the finished product.
•	23 July 2021	Changes to the SPC and labelling of the product to update the dosing and adverse reactions information for use in the target species.
•	02 February 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.
•	16 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	12 October 2020	Changes to the labelling and package leaflet.
•	01 July 2020	Submission of a new Ph. Eur. certificate of suitability from a new manufacturer.
•	19 March 2020	Renewal - UK as CMS

•	26 July 2019	Addition of secondary packaging site of the finished product.
•	25 April 2019	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 an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	25 April 2019	Addition of a site where batch control/testing takes place Addition of a secondary packaging site of the finished product Addition of a primary packaging site of the finished product
•	06 March 2019	Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	18 September 2018	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State. Deletion of a manufacturing site for an active substance.
•	27 April 2018	Change in RMS from UK to IE.
•	20 October 2017	Increase in the shelf-life of the finished product as packaged for sale from 2 years to 3 years.
•	15 December 2016	Addition of a secondary packaging site.
•	18 November 2016	Change in the invented name of the medicinal products from “Milbactor” to “Ziqamil vet” in Norway, Sweden and Finland.
•	25 August 2016	Change in test procedure for the active substance.
•	25 August 2016	Addition of a site of manufacture for the active substance.
•	09 June 2016	Submission of a new Ph. Eur. certificate of suitability