



Post Authorisation Assessments

Milbactor 12.5 mg/125 mg Tablets for Dogs Weighing at Least 5 kg Vm 01656/4074

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| • | 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) |
| • | 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. |
| • | 01 September 2021 | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 20 August 2021 | Updates to the Summary of Product Characteristics and product literature with regards to animal safety. |
| • | 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. |
| • | 15 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. |
| • | 11 March 2020 | Renewal - UK as CMS. |
| • | 05 June 2019 | Addition of a manufacturing 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 |

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| | | <p>manufacturer.</p> <p>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</p> <p>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</p> |
| • | 25 April 2019 | <p>Addition of a site where batch control/testing takes place</p> <p>Addition of a secondary packaging site of the finished product</p> <p>Addition of a primary packaging site of the finished product</p> |
| • | 06 March 2019 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 18 September 2018 | <p>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.</p> <p>Deletion of a manufacturing site for an active substance.</p> |
| • | 27 April 2018 | Change in RMS from UK to IE. |
| • | 18 October 2017 | Increase in the shelf-life of the finished product as packaged for sale from 2 years to 3 years. |
| • | 21 December 2016 | Addition of secondary packaging site of the finished product. |
| • | 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 | Addition of a new active substance manufacturer. |
| • | 25 August 2016 | Change to a test procedure for the active substance. |
| • | 09 June 2016 | Submission of a new Certificate of Suitability. |