Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Milbactor 2.5 mg/25 mg Tablets for Small Dogs and Puppies Weighing at Least 0.5 kg

Vm 01656/4073

| | | |
|---|---|---|
| • | 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.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>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.<br>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. |
| • | 09 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 manufacturer.<br>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.<br>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<br>Addition of a secondary packaging site of the finished product<br>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.<br>Deletion of a manufacturing site for an active substance. |
| • | 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. |