



Post Authorisation Assessments

Rycarfa 50 mg Tablets for Dogs

Vm 01656/4070

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| • | 27 February 2024 | Submission of an updated certificate of suitability. (NI) |
| • | 12 January 2023 | Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. |
| • | 17 April 2023 | Change to comply with Ph. Eur. reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number. |
| • | 23 February 2023 | Change to comply with Ph. Eur. reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number. |
| • | 28 December 2022 | Updated certificate of suitability from an already approved manufacturer. |
| • | 08 March 2022 | Minor change to an approved test procedure for the active substance. |
| • | 16 December 2021 | Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. |
| • | 12 November 2021 | Minor changes to an approved test procedure of the finished product. |
| • | 22 April 2020 | Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. |
| • | 25 February 2020 | Changes to the labelling and package leaflet. |
| • | 06 February 2020 | Addition of a manufacturer responsible for batch release including batch control/testing. Addition of a manufacturing site of the finished product. |
| • | 16 December 2019 | Deletion of manufacturing site for a finished product. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. |
| • | 10 December 2019 | Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer. |
| • | 12 November 2019 | Change in the manufacturer of a starting material used in the manufacturing process of the active substance. |
| • | 11 June 2019 | Change in the contact details of the QPPV of an existing pharmacovigilance system as described in the DDPS. |
| • | 19 February 2019 | Renewal – UK as CMS. |
| • | 10 May 2017 | Minor change to the restricted part of an Active Substance Master File. |

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| • | 19 May 2015 | Addition of UK local representative information to the package leaflet. |
| • | 08 September 2014 | Variation to extend the maximum holding time for the finished product packaged in PE/Alu triplex bags, from 2 months to 12 months. |