



Post Authorisation Assessments

Simparica Trio Chewable Tablets for Dogs >20–40 kg Vm 42058/5056

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| • | 01 February 2024 | One-off alignment of the product information with the latest version of the QRD template. |
| • | 18 October 2023 | Extension of the re-test period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier. |
| • | 01 August 2023 | Change in batch size of finished product. Change in batch size of finished product. Change in batch size of finished product. |
| • | 15 June 2023 | Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability. |
| • | 26 May 2023 | Addition of a new therapeutic claim: Treatment of sarcoptic mange (<i>Sarcoptes scabiei</i>) Addition of a new therapeutic claim: Treatment of demodicosis (<i>Demodex canis</i>) Addition of a new therapeutic claim: Prevention of establishment of thelaziosis (adult <i>Thelazia callipaeda</i>) |
| • | 26 April 2023 | Addition of an alternative supplier of a starting material. |
| • | 30 March 2023 | Minor changes to an approved test procedure for the finished product. |
| • | 21 March 2023 | Addition of a secondary packaging site of a non-sterile finished product. |
| • | 21 March 2023 | Addition of a primary packaging site of a non-sterile finished product. |
| • | 17 March 2023 | Addition of a manufacturing site for the manufacture of the finished product. |
| • | 08 February 2023 | The variation is to increase the holding time of the bulk product. |
| • | 30 November 2022 | For ticks (<i>I. ricinus</i>), the onset of efficacy is within 24 hours of attachment during the 35-day period after product administration. |
| • | 23 November 2022 | Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier. |
| • | 04 November 2022 | Correction in the name/address of a manufacturer of an active substance. |
| • | 29 September 2022 | Deletion of a supplier of packaging components. |
| • | 03 August 2022 | Deletion of the suppliers for the packaging components from the dossier. |
| • | 31 May 2022 | Change in the name of a supplier of starting material. |
| • | 09 March 2022 | Changes to a test procedure for the immediate packaging of the active substance. Change in manufacturer of the active substance. |
| • | 13 September 2021 | Updates to the Summary of Product Characteristics and product literature with regard to adverse reactions. |
| • | 07 June 2021 | Addition of a manufacturer of the active substance or addition of a site of manufacture |

