



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Simparica 40 mg Chewable Tablets for Dogs >10–20 kg Vm 42058/5051

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| • 23 February 2024 | Change in the shelf-life or storage conditions of the finished product. |
| • 22 February 2024 | One-off alignment of the product information with version 9.0* of the QRD templates. |
| • 22 December 2023 | Editorial changes to Part 2 of the dossier. Editorial changes to Part 2 of the dossier. Editorial changes to Part 2 of the dossier. Editorial changes to Part 2 of the dossier. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. Minor changes to an approved test procedure for the finished product. |
| • 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. |
| • 18 September 2023 | Minor changes in the manufacturing process of the drug product intermediate. Addition of a site for the manufacturing process of the drug product intermediate. |
| • 14 September 2023 | Change in batch size of the drug product intermediate. Minor changes to the registered method for the drug product intermediate. Minor changes to the registered method for the drug product intermediate. Minor changes to the registered method for the drug product intermediate. |
| • 31 July 2023 | Change in batch size of finished product. Change in batch size of finished product. Change in batch size of finished product. |
| • 17 April 2023 | Addition of an alternative supplier of a starting material. |
| • 20 February 2023 | Deletion of packaging components suppliers. |
| • 17 February 2023 | Additional indication: For reduction of the risk of infection with <i>Babesia canis canis</i> via transmission by <i>Dermacentor reticulatus</i> for 28 days after treatment. The effect is indirect due to the product's activity against the vector. Associated warning in Section 4.4 |
| • 22 December 2022 | Addition of a secondary packaging site of a finished product. |
| • 22 December 2022 | Addition of a primary packaging site of a non-sterile finished product. |
| • 31 October 2022 | Change in name and address of a manufacturer of the active substance. |
| • 19 October 2022 | Changes to labelling to include GB details in blue box. |
| • 23 August 2022 | Change in the name of a supplier of the active substance. |

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| | | Change in the name of a supplier of the active substance. Deletion of a supplier of the active substance. Deletion of a supplier of the active substance. |
| | <ul style="list-style-type: none">• 31 May 2022 | Change in the name of a supplier of starting material. |
| | <ul style="list-style-type: none">• 09 March 2022 | Changes to a test procedure for the immediate packaging of the active substance. Change in manufacturer of the active substance. |