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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Simparica 80 mg Chewable Tablets for Dogs >20–40 kg

Vm 42058/5053

	13 August 2024	Change in the synthesis of a non-pharmacopoeial excipient.
	18 May 2024	Alternate test method for a starting material added.
•	04 May 2024	Addition of a new specification parameter for a starting material.
•	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 Babesia canis canis via transmission by Dermacentor reticulatus for 28 days after treatment. The effect is indirect due to the product's activity against the vector. Associated warning in Section 4.4
•	30 December 2022	Change dimensions of the container or closure of a non-sterile finished product.
•	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. 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.
•	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.