



Post Authorisation Assessments

Simparica Trio Chewable Tablets for Dogs >40–60 kg

Vm 42058/5057

•	13 August 2024	Change in the synthesis of a non-pharmacopoeial excipient.
•	22 June 2024	Change in the address of a manufacturer of the finished product.
•	12 June 2024	Substantial changes in the updated version of the ASMF or the active substance part of the dossier. Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
•	14 May 2024	Indefinite renewal.
•	18 May 2024	Alternate test method for a starting material added.
•	11 May 2024	Change in name of manufacturer of starter material. Change in addresses for manufacturers of a starter material. Manufacturing site of a starting material deleted. Manufacturing site for a starting material deleted.
•	04 May 2024	Addition of a new specification parameter for a starting material.
•	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