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Post Authorisation Assessments

Simparica Trio Chewable Tablets for Dogs >40–60 kg

Vm 42058/5057

•	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 (Sarcoptes scabiei) Addition of a new therapeutic claim: Treatment of demodicosis (Demodex canis) Addition of a new therapeutic claim: Prevention of establishment of thelaziosis (adult Thelazia callipaeda)
•	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. ricinus), 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