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Post Authorisation Assessments

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

Bravecto 250 mg Chewable Tablets for Small Dogs (>4.5 – 10 kg)

Vm 01708/5021

13 October 2026	One-off alignment of the product information with version 3 of the GB QRD templates.
27 July 2026	Other changes to excipient parameter.
15 June 2026	Change in the name and address of a manufacturer for an excipient.
23 April 2026	Change in specification parameters of an excipient.
05 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
09 September 2025	Deletion of a non-significant specification parameter in the specification parameters of an excipient.
07 August 2025	Terms removed from adverse events table as outcome of signal management.
29 July 2025	Reduction in the testing frequency of an analysis.
04 July 2025	Deletion of a non-significant specification parameter for an active substance.
08 April 2025	Change in the specification parameters and limits of an excipient - Addition of a specification parameter with its corresponding test method.
28 April 2024	Change in the batch size (including batch size ranges) of the finished product.
24 January 2024	Alignment of product information with the national SPC/QRD template to align with QRD v 9.0 product information.
19 January 2024	Other changes relating to the excipients of the finished product.
23 August 2023	Minor change to sample preparation method as part of finished product testing.
13 June 2023	Unlimited renewal
18 November 2022	The grouped variation is to add two new therapeutic indications for Bravecto chewable tablets for dogs: for persistent tick killing activity from 7 days to 12 weeks after treatment for Ixodes hexagonus and for reduction of the risk of infection with Dipylidium caninum via transmission by Ctenocephalides felis for up to 12 weeks. The grouped variation is to add two new therapeutic indications for Bravecto chewable tablets for dogs: for persistent tick killing activity from 7 days to 12 weeks after treatment for Ixodes hexagonus and for reduction of the risk of infection with Dipylidium caninum via transmission by Ctenocephalides felis for up to 12 weeks
02 August 2022	To add an alternative irradiation test method for the pork liver flavour excipient from the SPF supplier used in Bravecto chewable tablets.
23 June 2022	Change in name of manufacturer of the active substance.
20 April 2022	Introduction of an alternative manufacturer of an excipient.
04 February 2022	Addition of a new therapeutic indication
21 December 2021	Change in the specification limits of an excipient.
03 September 2021	Changes to the labelling and/or package leaflet.