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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 Plus 250 mg / 12.5 mg Spot-on Solution for Medium-sized Cats (>2.8 – 6.25 kg)

Vm 01708/5028

•	05 September 2023	Addition of a new indication: Prevention of aelurostrongylosis. One-off alignment of the product information with version 9.0* of the QRD template.
•	17 April 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier. Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability.
•	12 December 2022	Unlimited renewal.
•	15 November 2022	Updated Ph.Eur certificate of suitability for an active substance. Updated Ph.Eur certificate of suitability for an active substance.
•	20 June 2022	Change in name of manufacturer of the active substance.
•	31 December 2021	To implement changes to the SPC and package leaflet following assessment of the PSUR.
•	30 July 2021	Addition of a pair of gloves per pipette in the carton box.
•	21 May 2021	Minor change in the manufacturing process of an immediate release solid oral dosage form. Minor change in the manufacturing process of an immediate release solid oral dosage form. Addition of a manufacturing site of the finished product. Addition of a secondary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
•	04 March 2021	Deletion of site where batch control takes place