Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS
Telephone +44 (0)1932 336911

Post Authorisation Assessments

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

Bravecto Plus 112.5 mg / 5.6 mg Spot-on Solution for Small Cats (1.2 – 2.8 kg)

Vm 01708/5027

4 June 2026	Submission of an updated CEP for the manufacture of an active substance.
23 March 2026	Submission of an updated Ph. Eur. CEP for an active substance.
01 March 2026	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex.
27 November 2025	Change to comply with Ph. Eur.
23 October 2025	Deletion of a manufacturing site for an active substance.
08 August 2025	Change to in-process tests or limits applied during the manufacture of the finished product. Minor change in the manufacturing process of the finished product.
15 July 2025	Deletion of a non-significant specification parameter for an active substance.
12 December 2024	Minor changes to an approved test procedure for the finished product.
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