



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Profender 96 mg / 24 mg Spot-on Solution for Large Cats Vm 06462/5009

10 February 2026	Addition of a new specification parameter with test method for an active substance. Addition of a new specification parameter with test method for a starting material. Change in the address name for an active substance manufacturer.
10 February 2026	Change to a test procedure for the finished product.
12 January 2026	Alignment of the product information with version 3.0* of the QRD templates. Additional subscripts and addition to adverse events approved.
16 December 2025	Submission of updated CEP for the manufacture of an active substance.
27 November 2025	Introduction of a second manufacturing and testing site to manufacture Emodepside active substance.
02 July 2025	Minor changes to an approved test procedure for the finished product.
07 February 2025	Addition of a manufacturer responsible for batch control and quality testing of the finished product. Addition of a manufacturer responsible for batch release of the finished product. Addition of a primary packaging site of the finished product. Addition of a secondary packaging site of the finished product.
07 February 2025	Change in test procedure for the immediate packaging of the finished product (including replacement or addition). Change in the batch size of the finished product: – downscaling down. Change in the batch size of the finished product: – up to 10-fold increase. Change in the specification parameters or limits of the finished product: – tightening of specification limits. Change in the specification parameters or limits of the immediate packaging of the finished product: – addition of a new specification parameter to the specification with its corresponding test method. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter. Changes to the quality part of the dossier: Deletion of - a non-significant specification parameter. Uniformity of dosage units is introduced to replace the currently registered method.
07 February 2025	Change in the manufacturing process of the finished product. Change in the specification limits of the finished product.

	Change to in-process limits applied during the manufacture of the finished product. Addition of a manufacturing site for the finished product.
12 December 2024	Updates to section 4.6.
18 May 2024	Submission of mock ups.
15 December 2021	Minor change in the manufacturing process of the finished product.
09 August 2021	Introduction of a new pharmacovigilance system.