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## **Post Authorisation Assessments**

For details of post authorisation assessments prior to 1<sup>st</sup> January 2021, please refer to the <u>EMA</u> website.

## Frontpro 68 mg Chewable Tablets for Dogs >10-25 kg Vm 04491/5012

30 April 2025	Change in batch size of active substance intermediate more than 10-fold increase compared to the originally approved batch size.  Change in batch size of active substance more than 10-fold
	increase compared to the originally approved batch size.
05 March 2025	Change in the batch size of the finished product.
18 November 2024	Update to SPC section 4.7 to indicate that the products can be used in breeding, pregnant and lactating female dogs. However, the safety of the veterinary medicinal product has not been established in breeding males. Change in distribution category from POM-V to NFA-VPS.
19 September 2024	Addition of a primary packaging site of a non-sterile finished product.
20 July 2024	Change in the name and address details of a manufacturer or supplier of the active substance.
28 April 2024	Addition of a manufacturer of a starting material used in the manufacturing process of the active substance where no Ph. Eur. Certificate of Suitability is part of the approved dossier.
11 January 2024	Unlimited renewal
13 October 2023	Addition of an alternative site responsible for manufacturing of the finished product. Editorial changes in section 3.1.2 are also included.
22 August 2023	Addition of a new supplier of a starting material used in the manufacturing process of the active substance.  Addition of a new supplier of a starting material used in the manufacturing process of the active substance.  Addition of a new supplier of a starting material used in the manufacturing process of the active substance.
06 June 2023	Change in batch size for intermediate used in the manufacturing process of the active substance.
13 April 2023	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
23 August 2022	Change in name of manufacturer of the finished product.
25 April 2022	Increase in batch size of the active substance.
25 April 2022	Change in composition of the immediate packaging for the active substance.
15 February 2022	Deletion of a supplier of packaging components or devices.
02 September 2021	Change in shape or dimensions of the container or closure (immediate packaging).  Minor change in the manufacturing process of the finished product.  Deletion of a non-significant specification parameter of an excipient.

25 March 2021	Change in the QPPV of an existing pharmacovigilance system
	as described in the DDPS.