



Post Authorisation Assessments

Fipnil Plus 134 mg/120.6 mg Spot-on Solution for Medium Dogs Vm 08749/5188

15 April 2026	Submission of a Ph. Eur. CEP for an active substance.
18 September 2025	Change in legal entity of MA holder from EU Pharmaceuticals Ltd, 37 Geraldine Road, London, SW18 2NR, United Kingdom to Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, H62 FH90, Ireland.
19 December 2023	Change in the name of a manufacturer of the finished product.
01 November 2023	Change in the limits of an active substance. Change in the specification parameters and/or limits of the finished product: - Change outside the approved specifications limits range.
10 March 2023	Unlimited renewal.
03 September 2021	Change in the manufacturing process of the finished product.
27 August 2021	Addition of a manufacturer of the active substance or addition of a site of manufacture.
23 November 2020	Increase in the shelf-life of the finished product as packaged for sale, from 2 years to 3 years.
09 October 2020	Replacement/Changes to a test procedure for the finished product.
28 July 2020	Update to the ASMF.
23 April 2020	Replacement to a test procedure for the finished product.
29 January 2020	Increase in batch size (including batch size range) of the finished product. Replacement to a test procedure for the finished product.
02 January 2020	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
09 December 2019	Addition of a new specification parameter with its corresponding test method of an active substance used in the manufacturing process of the active substance. Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 2 years.
25 November 2019	Changes to the labelling and/or package leaflet.
17 April 2019	Addition of distributor: Chanelle Animal Health Limited, 7 Rodney Street, Liverpool, L1 9HZ, United Kingdom
15 February 2019	Change in Legal Category from POM-V to AVM-GSL.

28 December 2018	Addition of a site where batch control/testing takes place. Addition of a secondary packaging site of the finished product. Addition of a primary packaging site of the finished product. Addition of a manufacturing site of the finished product.
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