



Post Authorisation Assessments

Fipnil Plus 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs Vm 39787/4017

•	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.

