

Post Authorisation Assessments

ITCH FLEA 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs Vm 39787/4012

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•	13 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.
•	20 October 2023	Introduction of new packaging for 1 pipette pack size presentation.
•	14 March 2023	Unlimited renewal.
•	16 June 2022	Change to the design of the mock ups for the previously approved 1 pipette pack size. Submission of mock ups for the 3 and 6 pipette pack sizes which have not been previously approved.
•	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.
•	24 December 2019	Increase in batch size (including batch size range) of the finished product. Replacement to a test procedure for the finished product.
•	21 October 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. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance.
•	09 July 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.
•	20 June 2019	Increase in the shelf-life of the finished product as packaged for sale, from 1 year to 2 years.
•	10 May 2019	Change in the invented name of the veterinary medicinal product from Chanonil Combo 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs to ITCH FLEA 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs

•	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.