



Post Authorisation Assessments

ITCH FLEA 402 mg/361.8 mg Spot-on Solution for Extra Large Dogs Vm 08749/5102

01 April 2026	Submission of a Ph. Eur. CEP for an active substance.
02 October 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.
04 April 2025	A new pack added for 3 and 6 pipettes with changes to the approved texts of the carton product information.
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.