



## Post Authorisation Assessments

### ITCH FLEA 268 mg/241.2 mg Spot-on Solution for Large Dogs Vm 39787/4011

|                   |   |
|-------------------|---|
| 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.<br>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.<br>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.<br>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.<br>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 268 mg/241.2 mg Spot-on   |

|                  |  |
|------------------|--|
|                  | Solution for Large Dogs to ITCH FLEA 268 mg/241.2 mg<br>Spot-on Solution for 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.<br>Addition of a secondary packaging site of the finished product.<br>Addition of a primary packaging site of the finished product.<br>Addition of a manufacturing site of the finished product. |