



Post Authorisation Assessments

Johnson's Fipronil Spot-on Solution for Large Dogs 268 mg Vm 39787/4053

•	04 March 2024	Change to the name a manufacturer of the finished product.
•	11 May 2023	Unlimited renewal.
•	16 June 2020	To add validation of microbial limit for the active substance. Addition of new packaging specification for the active substance.
•	05 March 2020	Update of active substance documentation.
•	26 July 2019	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product. Change in the specification parameters of the finished product. Addition of a manufacturing site of the finished product. Minor change in the manufacturing process of an immediate release dosage form. Additions to a test procedure for the finished product. Changes in the qualitative and quantitative composition of the immediate packaging of the finished product. Addition of a primary packaging site of the finished product.