



## Post Authorisation Assessments

### Enovex 0.5% w/v Pour-on Solution for Cattle

Vm 02000/4191

•	23 March 2023	Dimensions of the new 1 L container closure of a non-sterile finished product. Change in dimensions of a container of a non-sterile finished product. Change in dimensions of a container of a non-sterile finished product.
•	09 March 2023	Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier.
•	01 March 2023	Addition of a new 1 L spot-on presentation for the finished product.
•	28 October 2022	Change in distributor details from Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom to Norbrook Laboratories Limited, Carnbane Industrial Estate, Newry, Co Down, BT35 6QQ, Northern Ireland.
•	02 August 2022	Deletion of certificates of suitability for an active substance.
•	06 May 2022	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of pharmacovigilance assessment.
•	30 July 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
•	21 November 2018	Change in the specification parameters and limits of an excipient.
•	02 August 2018	Change in shape or dimensions of the container or closure (immediate packaging)
•	20 June 2017	Addition of a new specification parameter to the specification with its corresponding test method of the finished product Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	02 June 2016	Change in test procedure for the finished product.
•	21 August 2015	Submission of an updated certificate of suitability.
•	07 October 2013	Change of distributor details
•	11 December 2012	Addition of 2 manufacturers of the active substance Submission of an updated Ph. Eur. Certificate of Suitability for an active substance from an already

		approved manufacturer
•	21 August 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	24 July 2007	Renewal
•	27 February 2007	Change of legal category from PML to POM-VPS
•	27 July 2006	Addition of 250ml and 1L pack sizes
•	29 November 2005	Addition of a site of assembly
•	22 November 2000	Update licence particulars