



Post Authorisation Assessments

Robonex 5 mg/ml Pour-On Solution for Beef and Dairy Cattle Vm 02000/4340

•	03 January 2023	Change of Distributor address 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, BT35 6QQ, Co Down, Northern Ireland.
•	15 November 2022	Change in shape or dimensions of the container (immediate packaging) of a non-sterile finished product. Introduction of new backpacks. Change in dimensions of the container (immediate packaging) for the finished product. Change in shape or dimensions of the closure (immediate packaging) of the finished product- Introduction of a tamper evident cap to replace the conventional screw cap.
•	27 October 2021	Amendments to test procedure for the finished product.
•	21 May 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	21 May 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.
•	19 March 2019	Change in RMS from UK to BE.
•	02 October 2018	Change in distributor details. From Downland Marketing Limited to Norbrook Laboratories (GB) Limited, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, Northamptonshire, NN18 9EX, United Kingdom.
•	10 August 2018	Renewal – UK as RMS.
•	18 January 2017	Change in the manufacturer of a starting material. Tightening of specification limits of an active substance. Tightening of specification limits of an active substance. Addition of a new specification parameter to the specification with its corresponding test method used in the manufacturing process of the active substance. Minor change to the restricted part of an Active Substance Master File.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	17 October 2013	To extend the shelf life (as packaged for sale) from 18 months to 24 months.
•	30 May 2013	To change the name of the VMP from Eprivet to

		Anamex in AT, BG, CY, CZ, DK, EE, FI, EL, HU, LV, LT, MT, NO, PL, RO, SK, SI, SE. Also to change in name of the VMP from Eprivet to Noreprinec in ES, PT.
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