



Post Authorisation Assessments

Eprizero 5 mg/ml Pour-on Solution for Beef and Dairy Cattle

Vm 02000/4339

•	14 December 2023	Minor changes to an approved test procedure for the finished product. (NI)
•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	19 July 2023	Minor changes to an approved test procedure for the finished product. (GB)
•	22 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.
•	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.
•	07 October 2021	Update of test procedure for finished product.
•	22 August 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	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.
•	02 November 2018	Change in RMS from UK to IE.
•	12 July 2018	Renewal UK as RMS.
•	09 November 2016	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	Change in the shelf life of the finished product from 18 months to 2 years

