

## **Post Authorisation Assessments**

## Closiver 5 mg/ml/125 mg/ml Solution for Injection for Cattle and Sheep $_{\mbox{Vm}}$ 02000/4298

•	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.
•	16 August 2022	Deletion of certificates of suitability for an active substance.
•	07 June 2022	Update to AMSF.
•	17 September 2015	Renewal – UK RMS.
•	24 July 2015	Submission of an updated certificate of suitability.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	05 September 2014	Change to the distributor address.
•	21 November 2013	Change to update the withdrawal periods on the SPC and product literature following an EU Directive.
•	28 February 2013	To change the antioxidant limits at release.
•	27 December 2012	Submission of a new Ph. Eur. Certificate of Suitability from a new manufacturer. To update a Ph. Eur. Certificate of Suitability from an already approved manufacturer. To submit a new Ph. Eur. Certificate of Suitability for a new manufacturer.
•	30 November 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	26 May 2011	Extension Marketing Authorisation to change the invented name of the product, (in France only), from Closamectine Solution for Injection for Sheep, to Oestrocur Solution for Injection for Sheep.