



Post Authorisation Assessments

Closamectin Solution for Injection for Cattle

Vm 02000/3000

17 April 2025	Change in shape or dimensions of the container (immediate packaging):- Sterile medicinal products. Minor change in the manufacturing process of the finished product. Changes in the composition (excipients) of the finished product.
17 April 2025	Change in any part of the primary packaging material not in contact with the finished product. Change in dimensions of caps, not in contact with the finished product. Update of a test procedure to comply with the updated general monograph in the Ph. Eur. Minor change to an approved test procedure.
18 August 2023	One-off alignment of the product information with version 9.0* of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
17 February 2023	Deletion of certificates of suitability for an active substance.
23 January 2023	Removal of sheep as a target species.
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, BT35 6QQ, Co. Down, Northern Ireland.
21 June 2022	Update to AMSF.
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.
24 August 2018	Change in RMS from UK to IE.
24 July 2015	Submission of an updated certificate of suitability.
25 September 2014	Change of QPPV and update to the DDPS.
20 May 2013	Addition of sheep as a target species.
21 March 2013	Submission of two Ph. Eur. Certificates of Suitability for new manufacturers, and one Ph. Eur. Certificate of Suitability for an already approved manufacturer.
28 February 2013	To revise the limits of a product component.
18 January 2012	Renewal – UK as RMS
02 November 2011	To change the distributor.
13 January 2010	To increase the withdrawal period from 35 days to 49 days.

08 October 2008	To add new indications.
10 April 2008	Change in shelf life of the product.