Veterinary Medicines Directorate

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Post Authorisation Assessments

Closamectin Solution for Injection for Cattle and Sheep

Vm 02000/3000

•	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.