Veterinary Medicines Directorate

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Post Authorisation Assessments

Closamectin 5 mg/ml/125 mg/ml Solution for Injection for Sheep

Vm 02000/4262

•	23 November 2023	Introduction of a summary of the PSMF. (NI)
•	02 February 2023	Change in the invented name of the product in the UK from 'Closiver' to 'Closamectin'.
•	02 February 2023	Deletion of a food producing or non-food producing target species, not resulting from a safety issue.
•	31 January 2023	Deletion of certificates of suitability for an active substance.
•	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.
•	21 June 2022	Update to ASMF.
•	18 November 2021	Renewal- UK as CMS
•	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.
•	13 February 2019	Change in the invented name of the medicinal product in France. (Also contains changes made to QRD text to bring in line with current template (v8.1))
•	24 August 2018	Change in RMS from UK to IE.
•	28 December 2016	Addition of a manufacturer responsible for batch release. Addition of primary packaging site of the finished product. Replacement of a secondary packaging site of the finished product.
•	08 June 2016	Repeat use MRP
•	24 July 2015	Submission of an updated certificate of suitability.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	05 August 2013	Addition of sheep as a target species.

•	21 March 2013	Submission of an updated Ph Eur certificate of suitability for an already approved manufacturer, a new Ph. Eur certificate of suitability for a new manufacturer and a new Ph. Eur certificate of suitability for a second new manufacturer.
•	28 February 2013	To change the antioxidant limits at release.
•	30 November 2012	Changes to an existing pharmacovigilance system as described in the DDPS.
•	15 March 2012	Renewal procedure. United Kingdom as RMS.
•	29 October 2010	Change in the name of the veterinary medicinal product in France.
•	13 January 2010	To increase the withdrawal period from 35 days to 49 days.
•	15 July 2009	Variation to change the indications for fluke from 9 weeks to 7 weeks.