Veterinary Medicines Directorate

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Post Authorisation Assessments

Closamectin 5 mg/ml + 200 mg/ml Pour-on Solution for Cattle

Vm 02000/4280

•	04 May 2024	Minor changes to an approved test procedure for the finished product. (NI)
•	04 May 2024	Minor changes to an approved test procedure for the finished product. (GB)
•	23 January 2024	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
•	20 February 2023	Deletion of certificates of suitability for an active substance.
•	09 February 2023	Change in dimensions of the polyethylene backpacks. Introduction of alternative 2.5L and 5L backpacks. Introduction of tamper evident caps.
•	23 January 2023	Editorial changes to part 2 of the dossier.
•	22 November 2022	Change in the specification limits of the finished product.
•	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.
•	12 August 2022	Change in dimensions of the Polyethylene Backpacks. Introduction of alternative 2.5L and 5L backpacks. Introduction of tamper evident caps.
•	15 June 2022	Update to ASMF.
•	21 April 2022	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a PSUR.
•	26 October 2021	Update to the approved wording for the Summary of Product Characteristics (Section 4.5), and to the package leaflet (Sections 6 and 12).
•	30 April 2021	Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product. Minor change in the manufacturing process of the finished product.
•	03 December 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.

•	26 June 2019	Addition of a manufacturer responsible for batch release of the finished product.
•	26 June 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.
•	19 June 2019	Changes to the withdrawal period of the veterinary medicinal product.
•	21 March 2019	Change of RMS from UK to IE.
•	17 April 2018	Minor changes to an approved test procedure of the finished product.
•	29 December 2017	Change in the number of units in a pack within the range of the currently approved pack sizes of the finished product. Tightening of specification limits of a measuring or administration device for veterinary medicinal products.
•	15 December 2016	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	26 October 2016	Additional safety warnings added to the SPC.
•	07 October 2016	Submission of a new certificate of suitability.
•	30 July 2015	Submission of an updated certificate of suitability.
•	26 June 2015	Updates to section 4.6 of the SPC.
•	11 February 2015	Renewal Procedure.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	19 February 2014	Update of product literature to include a dosing table.
•	27 September 2013	To introduce a new manufacturer of the active substance.
•	12 July 2013	Change in the SPC and product literature in accordance with a Referral procedure.
•	14 December 2012	Updated Ph. Eur. Certificate of Suitability from an already approved manufacturer of an active substance, submission of a new Ph. Eur. Certificate of Suitability from a new manufacturer of an active substance, updated Ph. Eur. Certificate of Suitability from an already approved manufacturer of an active substance.
•	21 September 2012	Shelf-life of product as packaged for sale increased from 1 year to 18 months.
•	15 August 2012	To introduce new safety warnings to SPC and labelling.
•	02 November 2011	To change the distributor.
•	09 April 2010	To include an additional pack presentation of 500 ml, made of the same packaging material and within the range of the currently approved presentations for this product.
•	31 March 2010	To include the dosage table to the SPC and carton text.
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