Veterinary Medicines Directorate

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Post Authorisation Assessments

Norofas Pour-on Solution for Cattle

Vm 02000/4312

•	13 April 2024	Minor changes to an approved test procedure.
•	03 January 2023	Change of Distributor address 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.
•	18 August 2022	Change in dimensions of the Polyethylene Backpacks. Introduction of alternative 2.5L and 5L backpacks. Introduction of tamper evident cap.
•	08 August 2022	Change in specification limits for the finished product.
•	02 August 2022	Deletion of certificates of suitability for an active substance.
•	08 June 2022	Update to AMSF.
•	29 September 2021	Update to the SPC and Package leaflet; implementation of wording agreed by the competent authority (VMD).
•	24 August 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.
•	05 November 2020	Change in distributor details from Downland Marketing Limited, 15 Victoria Place, Carlisle, CA1 1EW to Downland Marketing Ltd, Main Mill, Warwick Mill Business Centre, Warwick Bridge, Carlisle, CA4 8RR.
•	28 October 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
•	19 June 2019	Changes to the withdrawal period of the veterinary medicinal product.
•	17 April 2018	Minor changes to an approved test procedure of the finished product.
•	12 January 2017	Deletion of Ph. Eur. certificates of suitability for an active substance manufacturer.

•	12 January 2017	Submission of a new Ph. Eur. certificate of suitability for an active substance manufacturer.
•	12 January 2017	Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product.
•	22 December 2016	Renewal – UK as RMS
•	15 January 2016	Change in the specification parameters and/or limits of the finished product
•	24 July 2015	Submission of an updated certificate of suitability.
•	27 March 2015	Change of distributor.
•	27 February 2015	Update to section 4.6 of the SPC and corresponding product literature.
•	25 September 2014	Change of QPPV and update to the DDPS.
•	23 April 2014	Change to distributor address.
•	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	Amendment of the milk withdrawal period statement to be in line with the flukicides referral outcome. An additional sentence on the potential for residues violations after allo-grooming by non-treated animals was also added.
•	13 December 2012	To update a Ph. Eur. Certificate of suitability from an already approved manufacturer of the active substance, to submit 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.
•	25 October 2012	Addition of a 500 ml HDPE container.
•	20 September 2012	Increase of shelf life of finished product from 1 year to 18 months.
•	02 August 2012	Addition of safety warnings to the SPC and product literature.
•	02 August 2012	Addition of a dosing table to section 9 of SPC.
•	12 October 2011	To change the name of the veterinary medicinal product in France only from Closamectin Solution Pour-On Pour Bovins to Closamectin Pour-On Solution Pour Bovins.