Veterinary Medicines Directorate

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Post Authorisation Assessments

Downland Fluke and Worm Oral Suspension

Vm 02000/4169

•	15 September 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. Or national pharmacopoeia of a member state.
•	04 May 2023	Update to Section 4.6 of the SPC and corresponding section of the PL.
•	10 March 2023	Editorial changes to part 2 of the dossier.
•	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.
•	21 June 2022	Change in the name and address details of an active substance master file (ASMF) holder.
•	13 June 2022	Change of specification(s) of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
•	23 December 2021	Change in the SPC, Labelling / Package Leaflet intended to implement the outcome of a procedure concerning PSUR.
•	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.
•	24 October 2019	Tightening of specification limits of an excipient. Addition of a new specification parameter to the specification with its corresponding test method of an excipient. Deletion of a non-significant specification parameter of an excipient. Change in the specification parameters and/or limits of an excipient. Change in the specification parameters and/or limits of an excipient.
•	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.
•	29 August 2018	Deletion of a supplier of packaging components or devices.

		Minor changes to an approved test procedure of the finished product. Minor changes to an approved test procedure of the finished product. Update of the test procedure to comply with the updated general Ph. Eur monograph. Increase in batch size (including batch size range) of the finished product.
•	28 March 2017	Deletion of a non-significant specification parameter of the finished product.
•	10 November 2014	Changes to an existing pharmacovigilance system as described in the DDPS.
•	01 September 2010	Change of withdrawal period for meat from sheep from 28 days to 5 days
•	09 June 2010	Update to SPC and Product Literature to include standard warnings for anthelmintics
•	04 September 2008	Changes to the SPC and Product Literature to bring in line with new legislation
•	07 March 2007	Change of legal category from PML to POM-VPS
•	10 April 2006	Renewal
•	12 October 2005	Addition of a manufacturing site of assembly
•	05 August 2005	Change in formulation
•	22 December 2003	Renewal
•	24 October 2003	Addition of manufacturer and assembler of the dosage form
•	13 December 2002	Addition of manufacturers of the active substance
•	19 June 2002	Change of distributor