Veterinary Medicines Directorate

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Post Authorisation Assessments

Levacide Low Volume 7.5% Oral Solution

Vm 02000/4081

•	04 May 2024	Replacement of a supplier of packaging components.
•	12 September 2023	Change to comply with an update of the relevant monograph of the ph. Eur. or national pharmacopoeia of a member state.
•	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.
•	22 June 2022	Change in the name and address of an active substance master file (ASMF) holder.
•	14 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.
•	21 August 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 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.
•	08 August 2012	Change in the address of the Distributor.
•	15 June 2010	Variation concerning corrections/simple text layout changes to the SPC and Product Literature.
•	09 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	20 February 2007	Variation to change the legal category from PML to POM-VPS.
•	26 June 2006	Renewal.
•	12 October 2005	Variation concerning the addition of a site of Assembly.
•	19 December 2003.	Renewal.
•	24 October 2003	Variation concerning the addition of a Manufacturer/Assembler of Dosage Form.
•	27 September 2000	Change in Manufacturer of Active Ingredient.

•	18 January 2000	Renewal.
•	06 October 1998	Additional Manufacturer of Active Ingredient.
•	07 March 1997	Additional Manufacturer of Active Ingredient.
•	14 July 1995	Update Safety Warnings.