



## Post Authorisation Assessments

### Levacide 7.5 % Solution for Injection Vm 02000/4049

•	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.
•	21 June 2022	Change in the name and address 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.
•	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 the address of the Distributor.
•	09 July 2008	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
•	07 November 2007	Renewal.
•	08 March 2007	Variation to change the legal category from PML to POM-VPS.
•	12 October 2005	Variation concerning the addition of a site of Assembly.
•	26 September 2003	Renewal.
•	10 February 2003	Variation to change Distributor.
•	05 December 2001	Change to Withdrawal Period.
•	05 December 2001	Renewal.
•	27 September 2000	Additional manufacturer of Active Substance.
•	07 March 1997	Manufacturer of Active Ingredient.
•	07 March 1997	Manufacturer of Active Ingredient.