



Post Authorisation Assessments

Levacide 7.5% Solution for Injection for Cattle and Sheep Vm 02000/4049

27 March 2026	Addition of a manufacturing site for the finished product. Alignment of the product information with version 9.0* of the QRD templates. Change to in-process limits applied during the manufacture of the finished product. Change in the batch size of the finished product. Change in the test procedure for the finished product. Change in the test procedure for the finished product. Change in the immediate packaging 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.
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.