Veterinary Medicines Directorate

Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911

# Post Authorisation Assessments

## Levacide Low Volume 7.5% Oral Solution

Vm 02000/4081

| | | |
|---|---|---|
| • | 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.<br>Addition of a new specification parameter to the specification with its corresponding test method of an excipient.<br>Deletion of a non-significant specification parameter of an excipient.<br>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.<br>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. |