Veterinary Medicines Directorate

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Post Authorisation Assessments

Levafas Diamond Oral Suspension

Vm 02000/4080

27 March 2025	Other changes to the active substance: - Substantial changes in the updated version of the ASMF.
04 May 2024	Container closure system dimensions corrected. Change in dimensions on the container closure system. Change in dimensions on the container closure system.
12 September 2023	Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a member state.
17 April 2023	Update to Section 4.6 of the SPC and corresponding section of the PL.
09 March 2023	Editorial changes to part 2 of the dossier.
March 2023	Update to Section 4.6 of the SPC and corresponding section of the PL.
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.
24 June 2022	Change in the name and address details of an active substance master file (ASMF) holder.
16 June 2022	Change of specifications of a former non Pharmacopoeial active substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State.
23 June 2020	Changes to Special Warnings for each target species, Special precautions for use, Adverse reactions (frequency and seriousness) and Amounts to be administered and administration route- in the SPC, Labelling or Package Leaflet, to implement the outcome of a procedure concerning PSUR.
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.
27 January 2017	Deletion of a non-significant specification parameter of the finished product
15 June 2010	Corrections to the SPC/Product Literature.
09 July 2008	Variations to bring the SPC/Labelling in line with the Veterinary Regulations, 2005.
20 February 2007	Change in the legal category from PML to POM-VPS.
10 April 2006	Renewal.
08 November 2003	Addition of a site of Assembly.
24 August 2004	Change in shelf-life of the finished product.
07 November 2003	Renewal.
27 October 2003	Change in product formulation.
27 June 2003	Addition of a Manufacturer/Assembler of Dosage Form.
24 October 2002	Change in product Withdrawal Period.
27 July 2000	Addition of a manufacturer of Active Substance.
24 February 2000	Change of Active Substance manufacturer.
02 October 1998	Change of Active Substance manufacturer.
22 July 1998	Renewal.
22 July 1998	Change in pack details of the finished product.
07 March 1997	Change of Active Substance manufacturer.
07 March 1997	Change of Active Substance manufacturer.
14 July 1995	Update Safety Warnings.