Veterinary Medicines Directorate

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

Post Authorisation Assessments

Proin 50 mg Chewable Tablets for Dogs

Vm 52366/5001

28 April 2026	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV.) Change in the pharmacovigilance system master file (PSMF) location.
04 November 2025	Change in legal entity of MA holder from Pegasus Laboratories UK Limited, Bridge House, 2 Bridge Avenue, Maidenhead, Berkshire, SL6 1RR, United Kingdom to Pegasus Laboratories Ireland Limited, 10 Mccurtain Hill, Clonakilty, County Cork, P85 K230, Ireland.
10 October 2025	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (NI)
05 August 2022	Unlimited Renewal
11 March 2022	Change in supplier of a flavour excipient and subsequent change to specification.
03 March 2021	Change in distributor details from Pegasus Laboratories UK Limited, Bridge House, 2 Bridge Avenue, Maidenhead, Berkshire, SL6 1RR United Kingdom to Forte Healthcare Ltd, Unit 9, Block 3, CityNorth Business Campus, CityNorth, Stamullen, Co. Meath, Republic of Ireland.
03 February 2021	Approval of mock ups following joint labelling with Ireland.
18 January 2021	Replacement of a site where batch control/testing takes place. Replacement of a manufacturer responsible for batch release of the finished product.
05 June 2020	Introduction of a new pharmacovigilance system.
10 March 2020	Change of MAH, from Cyton Biosciences Limited, 68 Macrae Road, Eden Office, Ham Green, Bristol, BS20 0DD to Pegasus Laboratories UK Limited, Bridge House, 2 Bridge Avenue, Maidenhead, SL6 1RR, United Kingdom.
30 May 2019	Changes to the date of the audit to verify GMP compliance of the manufacturer of the active substance