

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

## **Post Authorisation Assessments**

## Proin 15 mg Chewable Tablets for Dogs Vm 52615/4000

• (	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, City North Business Campus, City North, 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.
• 3	30 May 2019	Changes to the date of the audit to verify GMP compliance of the manufacturer of the active substance