

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

Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the **EMA** website.

GALLIPRANT 60 mg Tablets for Dogs Vm 52127/5018

•	04 September 2023	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product: - Change in the holding time of an intermediate or bulk product.
•	22 August 2023	'Pancreatic Inflammation' added to SPC and QRD Adverse Events sections.
•	17 July 2023	One-off alignment of the product information with version 9.0.
•	05 May 2023	Introduction of a new manufacturer of the active substance that is not supported by an ASMF.
•	31 August 2022	Unlimited renewal.
•	26 July 2022	Additional particle size testing site for the active substance.
•	12 November 2021	Changes in the SPC and Package Leaflet intended to implement the outcome of a periodic safety update report. (PSUR)
•	17 August 2021	Change in shape or dimensions of the container or closure (immediate packaging).