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Post Authorisation Assessments

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

GALLIPRANT 100 mg Tablets for Dogs

Vm 52127/5016

11 June 2026	Addition of a site where batch control or testing of the active substance takes place.
08 June 2026	Extension in the re-test period of an active substance.
16 February 2026	Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Editorial changes to part 2 of the dossier. Deletion of a non-significant specification parameter for a reagent. Deletion of a non-significant specification parameter for a starting material. Addition of a new specification parameter for a reagent with its corresponding test method. Addition of a new specification parameter for a reagent with its corresponding test method.
16 February 2026	Minor change to an approved test procedure for a starting material. Minor change to an approved test procedure for a starting material. Minor change to an approved test procedure for a starting material. Minor change to an approved test procedure for an intermediate. Minor change to an approved test procedure for an intermediate. Minor change to an approved test procedure for an active substance. Minor change to an approved test procedure for an active substance. Minor change to an approved test procedure for an active substance. Minor change in the manufacturing process of an active substance.
18 December 2025	Changes to the shelf-life or storage conditions of the finished product.
09 June 2025	Change in the name or address or contact details of a qualified person for pharmacovigilance (QPPV).
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).