Veterinary Medicines Directorate
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Post Authorisation Assessments

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

Zenalpha 0.5 mg/ml + 10 mg/ml Solution for Injection for Dogs

Vm 42810/5000

05 March 2025	Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate): – changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place.
14 December 2024	Change in test procedure for the finished product: - Other changes to a test procedure. (including replacement or addition).
21 September 2023	Introduction of a manufacturer of the active substance supported by an ASMF.
07 March 2023	Changes to a test procedure for a reagent used in the manufacturing process of the active substance. Minor changes to an approved test procedure for an in-process test for active substance. Minor changes to an approved test procedure for an intermediate used in the manufacturing process of the active substance. Minor changes to an approved test procedure for an intermediate used in the manufacturing process of the active substance.
02 November 2022	Addition of a quality control testing site.
18 October 2022	Other changes to the active substance: - Substantial changes in the updated version of the ASMF or the active substance part of the dossier.
26 September 2022	Addition of a secondary packaging site for the finished product.
30 September 2022	Change in colour of flip off caps for the finished product.
26 August 2022	Addition of a manufacturing site responsible for batch release.
23 August 2022	Minor changes to the restricted part of the Active Substance Master File.
24 May 2022	Minor changes to the manufacturing process in the restricted part of the Active Substance Master File.