Veterinary Medicines Directorate

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Post Authorisation Assessments

Felpreva Spot-on Solution for Small Cats (1.0 - 2.5 kg)

Vm 06462/5016

•	19 January 2024	Change to in-process tests or limits applied during the manufacture of the finished product.
•	29 September 2023	Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier: - Extension or introduction of a re-test period/storage period supported by real time data
•	29 September 2023	Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance: - Other changes. Changes in the manufacturing process of the active substance: - Other changes.
•	29 September 2023	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier: - Other changes
•	29 August 2023	Change in the name or address or contact details of: a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where specified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier. Minor changes: – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device. Minor changes: – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device. Minor changes: – to an approved test procedure for active substance, for the finished product, for the immediate packaging of the active substance or the finished product, or of a measuring or administration device.

		Minor changes: – to an approved test procedure, for a starting material, reagent or intermediate used in the manufacturing process of the active substance, or for an excipient.
•	25 August 2023	Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance:– downscaling down to 10-fold. Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance:– up to 10-fold increase compared to the originally approved batch size. Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance:– up to 10-fold increase compared to the originally approved batch size.
•	09 June 2023	Updates to section 4.6 of the SPC and the corresponding Section 6 in PL.
•	05 May 2023	Change in the shelf-life or storage conditions of the finished product: - Extension of the shelf life of the finished product - As packaged for sale.
•	03 May 2023	Addition of a secondary packaging site of a finished product.
•	14 July 2022	Extension of shelf life of the finished product as packaged for sale.