



## Post Authorisation Assessments

### Felpreva Spot-on Solution for Large Cats (> 5.0 – 8.0 kg) Vm 06462/5018

19 January 2025	<p>Change in a test procedure for the active substance.</p> <p>Minor change in the manufacturing process of the finished product.</p> <p>Change in the holding time of an intermediate or bulk product.</p> <p>Addition of a manufacturing site for part of the manufacturing process of the finished product.</p>
19 January 2025	<p>Change in test procedure for the immediate packaging of the finished product.</p> <p>Change in the packaging material of bulk product (intermediate product) not in contact with the bulk product formulation.</p> <p>Addition of a new specification parameter to the specification with its corresponding test method.</p> <p>Deletion of a non-significant specification parameter of an excipient.</p> <p>Deletion of a non-significant specification parameter in the specification parameters or limits of the immediate packaging of the finished product.</p> <p>Deletion of a non-significant specification parameter in the specification parameters or limits of the immediate packaging of the finished product.</p> <p>Deletion of a non-significant specification parameter of a reagent used in the manufacturing process of the active substance.</p> <p>Submission of an updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile active substance.</p>
19 January 2025	<p>Up to 10-fold increase in the batch size of the finished product.</p> <p>Addition of a manufacturer responsible for batch control or testing of the finished product.</p> <p>Deletion of a non-significant in-process test during the manufacture of the finished product.</p> <p>Deletion of a non-significant specification parameter of an excipient.</p> <p>Minor changes to an approved test procedure for active substance.</p> <p>Minor changes to an approved test procedure for active substance.</p> <p>Minor changes to an approved test procedure for the finished product.</p>

	<p>Addition of a manufacturer responsible for batch release of the finished product.</p> <p>Addition of a primary packaging site of the finished product.</p> <p>Addition of a secondary packaging site of the finished product.</p>
12 November 2024	Extension of shelf life for the finished product.
29 September 2023	<p>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:</p> <p>- Extension or introduction of a re-test period/storage period supported by real time data</p>
29 September 2023	<p>Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance: - Other changes.</p> <p>Changes in the manufacturing process of the active substance: - Other changes.</p>
29 September 2023	<p>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:</p>
29 August 2023	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
25 August 2023	Change in batch size (including batch size ranges) of active substance or intermediate used in the

	<p>manufacturing process of the active substance: – downscaling down to 10-fold.</p> <p>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.</p> <p>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.</p>
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.