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# Post Authorisation Assessments

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

## Solensia 7 mg/ml Solution for Injection for Cats

Vm 42058/5004

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| 01 April 2025 | Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance. |
| 12 February 2025 | Removal of the EU Local Representatives. |
| 14 December 2024 | Addition of a site where quality control testing of the finished product takes place. |
| 14 December 2024 | To update the analytical procedures for appearance, pH, osmolality, protein concentration and endotoxin testing.<br>To update the protocol for the generation of the WCB from the MCB.<br>To set the column efficiency testing of the packed bed to every 8th batch prior to use. The protein A resin qualification is increased from 89 to 210 cycles. |
| 11 May 2024 | Change in the classification of AE subsequent to the VSA report. |
| 21 February 2024 | Addition of a batch release site.<br>Minor updates to the Corden Pharma finished product manufacturing process. |
| 07 December 2023 | SPC Section 4.6, and QRD Section 7: added anaphylaxis with frequency very rare. |
| 02 June 2023 | To update the SPC/QRD as per the National SPC/QRD template v1. |
| 12 May 2023 | Addition of a secondary packaging site of a finished product.<br>Addition of a secondary packaging site of a finished product. |
| 27 April 2023 | Add an alternative ELISA commercial kit used to perform the registered specification testing requirement for the drug substance, frunevetmab, residual CHO host cell protein (HCP) parameter. |
| 22 November 2022 | Addition of alternative commercial cartridges and sample buffer for the Non-Reduced CE-SDS method. This method is used to perform the registered specification testing requirement for the formulated drug substance and drug product NR CE-SDS testing. |
| 19 October 2022 | Increase in batch size of active substance to 1,000 litres without process change. |
| 20 December 2021 | Changes to a test procedure for the active substance.<br>Addition to a test procedure for the finished product.<br>Change to in-process tests or limits applied during the manufacture of the active substance. |