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.

Solensia 7 mg/ml Solution for Injection for Cats

Vm 42058/5004

•	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. 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. Addition to a test procedure for the finished product. Change to in-process tests or limits applied during the manufacture of the active substance.